THE RISK ANALYSIS RESEARCH AND DEMONSTRATION ACT OF 1981

HEARING

BEFORE THE

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

OF THE

COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 24, 1981

[No. 58]

Printed for the use of the
Committee on Science and Technology

U.S. GOVERNMENT PRINTING OFFICE
87-143 O WASHINGTON : 1982

H701-29

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*On assignment to Budget Committee for 97th Congress.

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THE RISK ANALYSIS RESEARCH AND DEMONSTRATION ACT OF 1981

THURSDAY, SEPTEMBER 24, 1981

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 2318, Rayburn House Office Building, Hon. Doug Walgren, chairman of the subcommittee, presiding.

Mr. WALGREN. We will start and call the subcommittee to order, even though some of the members will be coming in a little later. We have witnesses who have time pressures and time constraints on their presence and we are very glad they are here and we want to accommodate their schedules as much as we possibly can.

This hearing is on H.R. 3441, known as the Risk Analysis Research and Demonstration Act of 1981. The bill has been authored by our colleague from Pennsylvania, Congressman Don Ritter, who has been interested in this subject since he came to Congress and has pursued it diligently and persistently. And although the wheels of Congress turn slowly, they do turn and we are making progress on this bill. It is something that I particularly, as chairman of the subcommittee, want to facilitate in every way.

Congressman Ritter in the last Congress was a member of the Committee on Science and Technology, of which this is a subcommittee, so his relationships with this committee are particularly close. We are delighted to have him participating with us and continuing to work on the passage of this bill.

Mr. RITTER. Thank you, Mr. Chairman, and I am delighted to be back with my colleagues.

Mr. WALGREN. Great.

Over the last several years the committee has conducted several hearings and other meetings on this subject. In July of 1979 we sponsored jointly with the Senate Commerce Committee and the American Association for the Advancement of Science a 2-day forum on risk benefit analysis in the legislative process. In May of 1980 we held hearings on comparative risk assessment which focused on an earlier version of this bill, and in July of this year we had, jointly with the Brookings Institution, a 1-day conference on public policy, science, and environmental risk.

In the context of those discussions, Mr. Ritter has revised this bill and refined it into the legislative proposal that we have before us today. It is cosponsored by Congressman George Brown, who is the former chairman of this subcommittee, and whose interest in

science in particular and the leading edge of science is well known by everyone who is involved in public policy in that area, and also by Congressman Don Fuqua, who of course is the chairman of the full committee.

We are pleased to welcome to the committee a number of distinguished witnesses today, including three Members of the House of Representatives who have a particular interest, a particular background, and a particular expertise in this area.

We want to move on this bill and bring it to the attention of the full committee and hopefully to the floor of the House of Representatives in some reasonable fashion consistent with the time demands on both those bodies. I hope we will be making progress with it, and the expressions of support from the other members of the subcommittee will certainly help to advance our expectation in that area.

I would ask unanimous consent that a copy of the bill, H.R. 3441, be inserted in the record at this point.

[The bill follows:]

I

97TH CONGRESS
1ST SESSION

H. R. 3441

To establish a coordinated program under the direction of the Office of Science and Technology Policy for improving and facilitating the use of risk analysis by those Federal agencies concerned with scientific and technological decisions related to human life, health, and protection of the environment.

IN THE HOUSE OF REPRESENTATIVES

MAY 5, 1981

Mr. RITTER (for himself Mr. FUQUA, and Mr. BROWN of California) introduced the following bill; which was referred to the Committee on Science and Technology

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A BILL

To establish a coordinated program under the direction of the Office of Science and Technology Policy for improving and facilitating the use of risk analysis by those Federal agencies concerned with scientific and technological decisions related to human life, health, and protection of the environment.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Risk Analysis Research and Demonstration Act of 1981".

FINDINGS AND DECLARATIONS

SEC. 2. (a) The Congress hereby finds and declares that—

(1) a number of Federal agencies have been mandated by law to protect, or provide information to protect, the public and the environment from harmful consequences of scientific and technological products and processes;

(2) scientific and technological decisions by Federal agencies, legally mandated to protect human life, health, and the environment, often involve rules to reduce risk to human life, health, and the environment;

(3) such regulatory decisions involve scientific, economic, social, and philosophical considerations;

(4) the bases for delegated decisions by agencies are often not clear or well understood by Congress and the public;

(5) these decisions increasingly involve an assessment and balancing of risks to human life, health, and the environment against the economic and social consequences of controlling these risks;

(6) improving the quality of the scientific component of such decisions is an important aspect of preserving the public's freedom of choice in weighing the social and philosophical values intrinsic in them; and

(7) the major purpose of public policy is to assure an equitable sharing of the risks and benefits of society and that therefore, analysis of the comparative risks to health and individual welfare among different groups can assist in setting broad public policy objectives.

(b) Accordingly, it is necessary for Federal agencies—

(1) to equip themselves with an effective means for securing information on and understanding the scientific basis for their regulatory decisions; and

(2) to utilize such information and understanding, whenever appropriate, as one factor in the assessment of matters before them pertaining to scientific and technological decisions related to protection of human life, health, and the environment.

(c) It is desirable to better delineate the scientific basis for agency decisions from their more subjective, judgmental aspects. Risk analysis will not provide a formula for setting public policies and making regulatory decisions, however, it may be a procedure by which such a delineation is facilitated. Risk analysis is basically a multistep process consisting first of a scientifically based risk assessment, which concentrates on the identification, probability, and consequences of risks, and secondly of a risk evaluation, which is more judgmental in nature and concentrates on decisions defining acceptable levels of risk. Since risk analysis is an emerging methodology

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there is a need to encourage basic and applied research in this interdisciplinary field; and the results of this research can contribute to enhancing the quality of the scientific component of the regulatory decisionmaking process.

(d) Scientific and technological decisions concerning risk normally involve consideration of alternative courses of action. Evaluation of these alternatives involves different risks and a balancing and ranking of the risks involved in these options; comparative risk analysis is a means by which a rational objectivity can be brought to the process of risk evaluation and the balancing of these alternatives. An important part of such decisions, and the ultimate question, is the acceptability of risk by the public; and comparison of risks represents a means by which levels of risk can be presented to the public in terms which facilitate freedom of choice in the weighing of nonquantifiable values.

(e) While many Federal agencies utilize risk analyses, there is presently no systematic, coordinated effort to establish risk analysis as an instrument in making regulatory decisions.

(f) Recent judicial decisions have demonstrated the need to further develop risk analysis in order to meet the rigorous standards of evidence and proof of cause and effect which are demanded by the courts.

(g) Improved transfer of data and information between Federal agencies and private and nonprofit corporations and institutions is necessary to improve and advance the quality of risk analysis.

PURPOSE

SEC. 3. It is the purpose of this Act to develop a comprehensive and coordinated research and demonstration program for risk analysis, taking into account the findings and declarations set forth in section 2, in order to—

(1) improve and facilitate the use of risk analysis as an instrument of regulatory analysis within those Federal agencies concerned with scientific and technological decisions related to human life, health, and the environment;

(2) develop a coordinated and systematic approach and methodology for the conduct and use of risk analysis by such Federal agencies;

(3) improve and create standards of quality, consistency, and scientific, as well as social, integrity in the development and use of risk analysis;

(4) identify areas requiring research to assist such Federal agencies in the use of risk analysis in regulatory decisionmaking; and

(5) establish within such Federal agencies a means to promote an understanding by the public of

the risk to life, health, and the environment of scientific and technological decisions made within their jurisdictions, by expressing those risks in terms of easily understood, everyday experience.

DEFINITIONS

SEC. 4. For the purposes of this Act—

(1) the term "risk" means the potential for realization of unwanted, negative consequences to human life, health, or the environment;

(2) the term "risk analysis" means the total process, including both risk assessment and risk evaluation, of quantifying a risk and finding an acceptable level of that risk for an individual, group, society, or the environment;

(3) the term "risk assessment" means the process of quantification of the probabilities and consequence values for an identified risk;

(4) the term "risk evaluation" means the complex process of developing acceptable levels of risk to individuals, society, or the environment;

(5) the term "comparative risk analysis" means a procedure of risk evaluation in which the probabilities and consequences of the risks associated with one course of action versus one or many alternative courses of action are compared, and which may include—

(A) comparisons of one particular action versus no action at all;

(B) comparisons of two or more different actions directed at achieving the same benefit;

(C) comparisons of the risks due to decisions to control to differing levels the contaminants in the environment;

(D) ranking of the risks that may result from any single course of action; and

(E) comparisons of the risks of any decision to control the effects of any course of action as compared to similar risks which may occur, or be present, due to natural occurrence;

(6) the term "Council" means the United States Regulatory Council;

(7) the term "Chairman" means the Chairman of the United States Regulatory Council;

(8) the term "Office" means the Executive Office of Science and Technology Policy; and

(9) the term "Federal agencies" means agencies within the Federal Government which are involved with regulatory decisions concerning scientific and technological regulatory decisions that affect human life, health, and the environment.

OBJECTIVES AND ESTABLISHMENT OF PROGRAM

SEC. 5. (a) The objectives of the program established under subsection (b) shall include—

(1) development of research programs on risk analysis within Federal agencies (particularly those specifically designated in subsections (b)(4) and (b)(5)), the objective of such program being to improve and develop techniques for measuring, gathering, analyzing, and evaluating data necessary to complete risk analyses and evaluations, with particular emphasis to be placed on the use of comparative risk in risk evaluation;

(2) integration and application of such research to the regulatory decisionmaking process to eliminate the deficiencies in that process identified in the findings made pursuant to subsection (c), and as otherwise appropriate;

(3) coordination between Federal agencies for the use of common research results and information required for risk analysis;

(4) development of strategies for the use of comparative risk—

(A) to set priorities on what specific actions or hazards should be the subject of regulation;

(B) to establish the most effective means of regulating in a specific area or for a specific substance; and

(C) to improve public understanding of decisions involving risk to human life, health, and the environment; and

(5) establishment of a procedure for the transfer and utilization of information and data between Federal agencies and private and nonprofit corporations and institutions.

(b) The President shall establish and direct in accordance with the provisions of this Act a coordinated program for the improvement and use of risk analysis, which shall—

(1) be designed to achieve the objectives set forth in subsection (a);

(2) direct the Office to provide oversight and guidance for the program;

(3) direct the Council to provide coordination, planning, and implementation of the program within Federal agencies;

(4) involve, where appropriate, Federal agencies involved in regulatory decisions or providing information for regulatory decisions, including but not limited to, the Food and Drug Administration, the Environmental Protection Agency, the Occupational Safety

and Health Administration, the Food Safety and Quality Service of the Department of Agriculture, the Nuclear Regulatory Commission, the Department of Energy, the Consumer Product Safety Commission, the Federal Aviation Administration, and the Department of Transportation; and

(5) involve, where appropriate, the National Science Foundation and other agencies with basic and applied research programs applicable to the improvement of risk analysis.

(c) The Council, within six months after the enactment of this Act, shall present to the Congress a plan which shall include—

(1) a review of the extent, type, and quality of risk analysis presently being carried out within the Federal agencies specifically designated in subsection (b)(4), and its use in the regulatory decisionmaking process;

(2) a review of the extent, type, and quality of risk analysis research being carried out by the Federal agencies specifically designated in subsection (b)(4), and the procedures within those agencies for coordinating this research with the regulatory decisionmaking process;

(3) for purposes of comparison with the findings to be made under paragraphs (1) and (2), a brief review of the extent, type, and quality of risk analysis and risk analysis research presently being carried out outside Federal agencies;

(4) recommendations for specific areas of emphasis for research conducted within Federal agencies, and for the funding of such research outside such agencies by the Federal Government, Federal agencies, the National Science Foundation, and the National Institutes of Health;

(5) recommendations for a coordinating mechanism to transmit and share research results between Federal agencies, between Federal agencies and other public agencies, and between Federal agencies and private and nonprofit corporations and institutions;

(6) a program plan for prototypical risk analysis demonstrations which shall be carried out within the Federal agencies specifically designated in subsection (b)(4);

(7) identification of the areas where the use of the results of a risk analysis would either be limited or prohibited by current law, regulation, or practice;

(8) identification of approaches to risk analyses or the use of these analyses in regulation;

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(9) a review of the present organizational structures of the Federal agencies specifically designated in subsection (b)(4), noting changes necessary to implement the use of risk analysis; and

(10) recommendations for increasing public awareness and understanding of risk.

RESEARCH

SEC. 6. (a) The Federal agencies specifically designated in section 5(b)(4) shall recommend to the Council research that should be done by such agencies to meet the objectives stated in section 5(a).

(b) The National Science Foundation, on the basis of work done by the National Academy of Sciences and other individuals and institutions both inside and outside the Federal Government, shall recommend to the Council a program of research directed at strengthening the basic and applied sciences required to support Federal agencies in utilizing risk analysis methods in regulatory decisionmaking. Such program shall include—

(1) a consideration of new and improved methods for gathering data;

(2) a consideration of methodologies for analyzing and utilizing such data;

(3) a provision for research into the social aspects of using comparative risk analysis in regulatory decisionmaking; and

(4) an identification of the areas of emphasis for the research programs of the National Science Foundation and other Federal agencies.

(c) The Chairman shall have the responsibility to coordinate the research programs recommended by Federal agencies pursuant to subsection (a) and the research programs recommended by the National Science Foundation pursuant to subsection (b).

DEMONSTRATION PROJECTS

SEC. 7. (a) The Council shall direct each of the Federal agencies specifically designated in section 5(b)(4) which promulgate regulations to undertake a prototypical risk analysis study. These studies should utilize presently available information and techniques, or new developments where available, and wherever appropriate should include the following elements:

(1) Comparison of risk of alternative courses of action.

(2) Delineation of scientific from policy judgments.

(3) Utilization of some form of sensitivity analysis to highlight the importance of assumptions and uncertainties.

(4) Identification of limitations placed on the analysis due to relevant organizational and statutory constraints.

(5) Highlighting the importance of tradeoffs that the decisionmaker must confront in order to cope with the problem posed in the particular risk analysis prototype.

(6) Suggestions of how additional information, or changes in statutory language and organizational structure, could change the strategy chosen to cope with this problem.

(7) Discussion of how comparative risk analysis could be utilized to make the public aware of the relevance of the decisions, including a consideration of factors such as voluntary versus involuntary nature of similar risks, manmade versus natural risks, and necessary versus unnecessary risks.

(8) Delineation of information concerning the different levels of risk to health and welfare among different groups within the population, including consideration of socioeconomic, location and other pertinent factors, to assist in the equitable sharing of risks and for benefits to be realized from the regulatory process and the implementation of public policy.

(b) Such studies shall be completed within one year after the date of the enactment of this Act, and shall be published in a timely manner and made available to experts in the field and the public at large.

(c) The Chairman shall have responsibility for analyzing and evaluating these prototypical risk analyses, with particular note to be made of problems common to the studies.

REPORT

SEC. 8. (a) The Chairman shall issue a report to the Congress within two years after the date of the enactment of this Act, which shall include—

(1) a summary of the findings made pursuant to section 5(c);

(2) recommendations for future research necessary to achieve the purposes and objectives of this Act;

(3) recommendations for research funding methods, including base and incremental options;

(4) recommendations for legislation needed to implement and facilitate the use of risk analysis within Federal agencies;

(5) recommendations for nonlegislative changes, including organizational changes, to implement a policy of risk analysis within Federal agencies;

(6) recommendations that will result in the improved transfer of risk related research and information

between Federal agencies and private and nonprofit corporations and institutions; and

(7) recommendations for methods and procedures by which public understanding and appreciation of risk and regulatory decisions related to risk can be improved and increased.

(b) A preliminary draft of such report shall be circulated by the Chairman for review and comment by organizations and representatives of both public and private interests, and any comments made shall be included in the final draft of such report submitted to Congress.

ADMINISTRATION

SEC. 9. The Council may employ and fix the compensation of officers and employees, retain experts and consultants, and utilize services, personnel, equipment, and facilities to the same extent as the Council on Wage and Price Stability under the Council on Wage and Price Stability Act.

AUTHORIZATION OF APPROPRIATIONS

SEC. 10. There is hereby authorized to be appropriated for the term of this program, not to exceed two years, such sums, not to exceed $1,500,000 to the Council, $50,000 to the Office, and $150,000 to the National Science Foundation, for the purpose of carrying out this Act.

Mr. WALGREN. I now want to turn to the Honorable James Martin, our colleague, who will be the leadoff witness today. We certainly appreciate your interest in this and your taking the time to develop the legislative record with us.

Proceed as you would.

STATEMENT OF HON. JAMES G. MARTIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. MARTIN. Thank you very much, Chairman Walgren. I do want to thank you for calling this hearing, and for your leadership in moving this legislation.

I had an opportunity, I believe it was a year ago, to testify at an earlier hearing, and it is not necessary for me to repeat the same remarks that I had then because that is already in your record. But I do want once again to commend the author of the legislation, our colleague, Mr. Ritter, for his work. It is sound legislation and I certainly will be supporting it and doing all I can to build support for it among our Members of the House of Representatives.

I also want to commend you, Mr. Chairman, for your enthusiasm in moving the legislation forward so that it can be considered.

I think there are many of us in the Congress, and certainly many outside the Congress, who believe that it is long overdue for this Congress to address the question of not only risk benefit comparisons but I think, more critically, the question of analysis, assessment, and evaluation of risks themselves. In the past, we have had a variety of policies associated with risks in different areas. Certainly with regard to cancer factors, carcinogens, there has been a range of policies, some that have evolved with regulatory efforts, and others spelled out specifically in the well-known Delaney clause in the Food, Drug and Cosmetic Act, which as you know applies to food additives essentially.

It has been my view that it is not only not good policy, but it certainly is not good science for us in essence, to try to ban a substance to the fullest reach of technological capability without regard to anything other than a finding of carcinogencity. I think we have to take into account relative potency; I think we have to take into account differences in metabolism and defense mechanisms, as well as similarities of those physiological factors between the test animals and humans. We have to take into account the actual exposures of the entire population as well as subgroups of our population, particularly where those working with potential exposure to higher concentrations are concerned.

I think that that is more important than the comparison of benefits. As you know, it is very difficult in the first place to compare benefits in a precise way. To begin with, the numbers aren't precise themselves, and second, the units of measure of risk and benefit are often far different and difficult to interconvert. Nevertheless, that ought to be taken into consideration. It is a greater error to ignore a consideration of benefits, to ignore a consideration of what alternatives might be available.

It would be my hope that the study which is to be implemented by this legislation would develop for us a means of determining levels of risk so that the Congress can address, in a policy way, what levels in different areas of hazard would be termed as unac-

ceptable and what we would do about it. Those would be policy questions that would have to come before the Congress.

But for those policy decisions to be useful, for them to be sound, for them to be rational, it seems to me they have to be based on good science. There has to be a better science base for the decisions that are to be made in pursuit of the policies that the Congress sets.

I think that while it is the responsibility of Congress to set the overall policy, we should give greater attention and greater consideration to the views of the scientific communities as to what the meaning is of some of the very small numbers that we are turning up in these areas of testing for possible risk.

I would hope, also, that the study would recognize and reaffirm the value of peer review in evaluating evidence before it is published and before policy is made on it—though, of course, that will be up to the panels that will be conducting these studies to come to their own conclusion. But it seems to me very important that, if the science base is going to be a reliable one, it should be subjected to that cross-examination that is a part of the publication process within the scientific community.

Mr. Chairman, there is quite a battle going on in the "trenches," so to speak, between governmental authorities, between industrial groups, between consumer groups, including those who actually consume substances in question, as to what risk policy should be developed. There have been too many cases of intimidation of individual scientists on all sides who have spoken out. There is an effort underway right now to try to determine which scientists receive any more whatsoever from any industrial group so that they can be lambasted. There are other stories from time to time, far too often, of scientists within Government who differ with the orthodoxy that has prevailed or that prevails from time to time. Therefore, it would be my hope that we can rise out of that morass of counteraccusation and efforts to intimidate individual scientists with legislation of this sort, so that we can proceed on hopefully a higher plane.

It is for that reason that I would urge the subcommittee to—in addition to the study which it is seeking to implement—to take into greater account the views of the scientific learned societies, by determining what their consensus views are about the particular risk question before us. That would be one way of avoiding the focus of intense pressure on individual scientists, by contacting those societies, I think you can get a better input as to the view of scientists about these matters without subjecting individuals to reprisals. I would hope that you would do that, and I would hope that, although you're having just one day of hearings, that you would at least allow the record to be open for any policy statements that have already been prepared in the last few years by these learned societies so that those could be appended to the record. That would not allow them to be subject to cross-examination, but I think their views would be very valuable and helpful in supporting the legislation which is before you.

Mr. WALGREN. Certainly, without objection, we would do that and hope that interested parties will submit views, comments and suggestions. We would like them very much for the record.

We are having only 1 day of hearings because we really have had some in this area before and we hope that the whole record, taken together, will support the action that the bill proposes.

Mr. MARTIN. I believe that it will, Mr. Chairman.

Mr. WALGREN. How do you feel about the amounts of money that are authorized in the bill, where we apparently are suggesting that over a 2-year period the regulatory group have at its disposal about $1.5 million, and the Office of Science and Technology, $50,000; and the National Science Foundation, $150,000? It is tough to ask for any money in Washington these days, and yet it is also true that hopefully society understands you can cut off your nose to spite your face and it is important to try to put the pieces in place that would allow the Government to function best.

Do you see this kind of expenditure as being justified in the current environment?

Mr. MARTIN. Mr. Chairman, I was going to say that while I have not examined any detailed budget preparation as to what the particular cost would be, I can give you a general assessment that it would certainly be justifiable.

We are on the threshold, on the verge of addressing and, hopefully, making some very important changes, very difficult changes, for a political body such as the U.S. Congress to make regarding how we deal with risks, how we determine them, how we evaluate their potential, and what we do about them. And in order for us to make those changes, it seems to me we have to have the strongest bases worked out for those so that the changes we make will be sound.

I think the chairman knows that there soon are going to be hearings before the Committee on Agriculture, and the Committee on Interstate and Foreign Commerce has had an interest in this area. I believe the chairman also serves on that committee. The Congress has to be very cautious not to proceed just on the basis of an outcry or a headline or some sudden impetus, but to proceed very cautiously so that we come up with sound legislation.

I think this kind of study is needed as a basis for that, so I would certainly support and try to assist in justifying to other Members the cost. There is no need to do a study if it's not going to be done properly.

Mr. WALGREN. Certainly in my judgment there has been so much heat and so little light on many of the areas that should be dealt with by science and some position to start from other than whether or not it's in my particular interest or some other person's particular interest.

It seems to me that one of the problems in any society is trying to get people to understand what the situation looks like from the other person's point of view. In the area of risk, almost as the word implies, you're talking about something that may or may not happen to me or may or may not happen to anyone in this room, but might happen to somebody. And if we don't look beyond what our own particular risk may be, we may not appreciate the severity of the problem.

At the same time it is also true that we do want to run some risks. There are risks that do make sense to run. I certainly hope that if this area of science could develop we could make much more

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knowledgeable decisions about which ones to run and which ones not to run.

Mr. MARTIN. Also, Mr. Chairman, which ones to allow an informed public to make their own choices on, to the extent the choices are theirs to make; that is, where there are avoidable risks that would be subject to the choice of the individual.

Mr. WALGREN. We certainly appreciate your opening statement.

I would like to recognize Mr. Ritter for either a combination of questioning and discussion or opening statement, however you would like to proceed, Don.

Mr. RITTER. Fine.

I personally would like to thank Dr. James G. Martin from North Carolina, a very distinguished member of the House Ways and Means Committee, for the kind of leadership that he has provided in this area of socially important, scientific questions. Dr. Martin, since he came to the Congress, has been very active in this area. He is formerly a chemistry professor, a scientist, and he and I—and I think there is one other—are the only three formerly practicing technical professionals in the U.S. Congress, and we're probably one of the loneliest groups around, surrounded by a sea of attorneys. One sometimes wonders "whither thou goest, science." Nevertheless, we stay in there slugging away.

Dr. Martin has made some very significant contributions in the area of the Delaney clause, and as he has mentioned, the Food and Drug Act will be coming back before the Energy and Commerce Committee. The questions of risk assessment and really risk comparison—putting the particular risk in perspective by examining what the scientific data says—will all be coming up. I think Representative Martin has provided over the years a substantial base for Congress to consider this question.

I personally agree with some of the points he made, the idea that whatever we do has a scientific basis or relationship or importance, and has to be based on valid science. We have had over the last decade or so some very substantial examples of invalid, nonpeer reviewed science that under close scrutiny didn't stand up.

I think his point about incorporating the views of the various scientific, professional societies is a very important one, because as we all know, anybody can hire a "gun," a scientist, and come out with a position on an issue. The question is, That person may be a chemist, but what is the view of the American chemical society; what is their view representing perhaps 110,000 chemists? Now, that may be a very important view to integrate into the scientific perspective on an issue.

The same is true of our engineering societies, who have hundreds of thousands of members, many of which have taken stands on the critical issues of our time, whether it is nuclear power, clean air, food and drug or health and occupational safety. I think we need to further consult with those considered opinions—not that we have to be forced to accept their judgments, but that we simply listen to what a reasonably broad perspective of the community is saying. So I just wanted to thank Dr. Martin again and agree with some of his statements.

Mr. WALGREN. Thank you, Mr. Ritter.

The Chair would want to recognize Mr. Gregg at this point for any comments he might have.

Mr. GREGG. I have no comments, Mr. Chairman.

Mr. WALGREN. Well, thank you very much on behalf of the committee. We certainly appreciate your interest in this and look forward to working with you in the process.

Mr. MARTIN. Thank you, Mr. Chairman.

Mr. WALGREN. The next witness will be the Honorable Donald Ritter, the author of the legislation. As I said at the outset, Mr. Ritter is sort of in a hybrid capacity here. As a former member of the committee, he is always extended the courtesy of participating with the committee and we value that. On the other hand, you might want to formally take the witness chair, if you would like.

Mr. Ritter is the author of this legislation and is really, from the Science and Technology Committee's viewpoint, the person who is most responsible for pursuing the other members of the committee with this idea and developing it. So we welcome you and want to express our appreciation for your past work on this and look forward to working with you as we go forward now.

STATEMENT OF HON. DON RITTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. RITTER. Thank you very much, Mr. Chairman.

Let me personally extend my thanks and my sincere appreciation to you for following through with this very important subject, and for your leadership in calling these hearings and getting the very distinguished list of witnesses together.

I might add that having been a member of the Science and Technology Committee and still having many warm places in my heart for its membership and its activities, I would like to let you all know that it was with some duress and some constraints that my membership on that committee terminated, and that had I had my druthers, I would be doing what I am doing with Energy and Commerce, but I still would be on the Science and Technology Committee. There is a thing called ratios amongst members and amongst committee positions, and I think I got caught last spring in the ratio crunch.

Since coming to Congress, and really even before as a practicing technical-professional, I have been concerned about the ability of our society to put hazards into perspective. I fully recognize the difficulties that face our agencies involved with regulatory rulemaking. I fully recognize the intense pressures from different interested parties, the intense pressures that result from the media, and the media's interest in this subject; the intense pressures from people who could be severely at risk. My sincere hope is that the legislation that we are considering today would assist in helping regulatory agencies to set priorities and focus on those issues that present the greatest hazard to our health or the environment. That has got to be a goal. Considering that our regulatory resources are limited, that we are looking forward to unlocking the regulatory entanglement and obstacle course for sure, in order to perform in the best possible way for the American people, we have got to protect them as best we can. We can only do that if we take a very fair and critical look at the hazards that we face and we regulate those which are of the greatest danger to the people.

These are difficult goals, and the temptation to jump to conclusions and regulate out of intense pressure coming from a particular corner is very hard to resist.

I view risk assessment and risk comparison as useful tools to provide a greater technical insight to political decisions that must be made regarding the protection of health, safety, and the environment. I believe that my bill offers a structure to organize and demonstrate the value of this methodology and both complements and gives impetus to existing risk assessment projects presently active in the Federal agencies today.

I want to emphasize risk comparison here. I personally am not involved or really that interested in the ultimate detail of how to do a risk assessment. But I do know that putting a hazard in perspective demands some reasonable ability to understand the magnitude of a particular risk. But it is the putting hazard in perspective that demands us to compare risks.

People, citizens, have to understand that every day from the time they get up and take a shower in a bathtub that doesn't have a friction bottom, they are taking risks, substantial risks in terms of insurance statistics. As they drive to work, they are taking a substantial risk in terms of any statistics. We know 55,000 people a year are killed on the highways. As they walk downstairs they are taking substantial risks—some 15,000 people are killed or seriously injured walking down stairs. What are we going to do? Ban down staircases and have every building equipped with elevators to take people down?

Smoking and drinking involves severe risks. At a recent meeting on the Clean Air Act in my own congressional district, there was a lung specialist, a pulmonary specialist, who testified that all of the Clean Air Act provisions and all the Clean Air Act hazards are pale in comparison with individuals' smoking habits.

Now, that is not to say that we are not interested in regulating those additional hazards that are posed by different elements of our society to our air in the Clean Air Act. But I think it is useful to know that if a bunch of people come into a room and are smoking, and are screaming against any sort of changes in the Clean Air Act, that they should realize they're dealing with a rather limited effect compared to their own individual risk-taking.

I believe that my bill will provide some demonstration of a methodology that will, in the final analysis, save resources at our Federal agencies. The last thing I want to do is create some new kind of bureaucratic impediment on heavily burdened agencies. It is the concept, it is the approach, it is the usefulness of the tool; it is not an end in itself. I think by focusing regulatory efforts on the greatest hazards, it can set the priorities needed to improve the efficiency of the regulatory process, makes best use of the regulatory dollars, and indeed, in the final analysis, better protects the American people.

I would like to end here and allow the subcommittee to hear our distinguished guests. Mr. Chairman, thank you again, and I look forward to this hearing and later on to the inclusion of the concepts of risk assessment and risk comparison as a part of our shared goal of intelligent regulatory reform.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Ritter follows:]

TESTIMONY OF CONGRESSMAN DON RITTER BEFORE THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY HEARING ON H.R. 3441, RISK ANALYSIS AND DEMONSTRATION ACT OF 1981, SEPTEMBER 24, 1981

THANK YOU MR. CHAIRMAN, IT'S GOOD TO BE BACK WITH MY COLLEAGUES IT'S ESPECIALLY GOOD TO BE BACK TO ATTEND THIS HEARING. SINCE COMING TO CONGRESS, AND BEFORE AS A TECHNICAL PROFESSIONAL, I HAVE BEEN CONCERNED ABOUT OUR ABILITY AS A SOCIETY TO PUT HAZARDS INTO PERSPECTIVE. I FULLY RECOGNIZE THE DIFFICULTIES THAT FACE OUR AGENCIES INVOLVED WITH REGULATORY RULE MAKING. MY SINCERE HOPE IS THAT THE LEGISLATION THAT WE ARE CONSIDERING TODAY WOULD ASSIST IN HELPING REGULATORY AGENCIES TO SET PRIORITIES AND FOCUS ON THOSE ISSUES THAT PRESENT THE GREATEST HAZARD TO OUR HEALTH OR THE ENVIRONMENT. AS WE ALL KNOW, THOSE ARE DIFFICULT GOALS TO ATTAIN AND THE TEMPTATION TO JUMP TO CONCLUSIONS IS SOMETIMES A HARD ONE TO RESIST. I VIEW RISK ASSESSMENT AS A USEFUL TOOL TO PROVIDE SOME GREATER TECHNICAL INSIGHT TO POLITICAL DECISIONS THAT MUST BE MADE REGARDING THE PROTECTION OF HEALTH AND THE ENVIRONMENT. I BELIEVE THAT MY BILL OFFERS A STRUCTURE TO ORGANIZE AND DEMONSTRATE THE VALUE OF THIS METHODOLOGY AND BOTH COMPLEMENTS AND GIVES IMPETUS TO RISK ASSESSMENT PROJECTS THAT ARE ONGOING IN OUR FEDERAL AGENCIES RIGHT NOW.

LET ME ASSURE YOU THAT ADDING ANOTHER REQUIREMENT TO OUR ALREADY HEAVILY BURDENED AGENCIES IS THE LAST THING I WANT TO DO. I BELIEVE THAT MY BILL WILL PROVIDE SOME DEMONSTRATION OF A METHODOLOGY THAT WILL, IN THE FINAL ANALYSIS, SAVE RESOURCES AT OUR FEDERAL AGENCIES. BY FOCUSING REGULATORY EFFORTS ON THE GREATEST HAZARDS, IT WILL HELP SETTING THE PRIORITIES NEEDED TO IMPROVE THE EFFICIENCY OF OUR REGULATORY PROCESS.

I WANT TO BE BRIEF TO ALLOW THE SUBCOMMITTEE TO HEAR OUR DISTINGUISHED GUESTS. MR. CHAIRMAN, THANK YOU AGAIN, AND I LOOK FORWARD TO THIS HEARING, TO THE CONCEPTS OF RISK ASSESSMENT, AS ONE PART OF THE GOAL OF INTELLIGENT REGULATORY REFORM.

Mr. WALGREN. Thank you, Mr. Ritter.

Please come back and join us here at the table, and then after the next witness, we might be able to have some exploration with you by Mr. Skeen or others in followup of your statement.

We were also hoping to have before the committee this morning the distinguished ranking minority member of the Committee on Agriculture, our colleague Mr. Bill Wampler. He is unable to be here at this time and I ask unanimous consent that his prepared remarks be entered in the record.

[The prepared statement of Congressman Wampler follows:]

STATEMENT BY REPRESENTATIVE WILLIAM C. WAMPLER OF VIRGINIA

BEFORE THE SUBCOMMITTEE ON SCIENCE, RESEARCH, AND TECHNOLOGY

ON H.R. 3441, RISK ANALYSIS RESEARCH AND DEMONSTRATION ACT OF 1981

September 24, 1981

Mr. Chairman, I wish to add my support for the bill, H.R. 3441, the Risk Analysis Research and Demonstration Act of 1981, offered by my Colleague, Congressman Don Ritter of Pennsylvania, which is now before your subcommittee.

Any measure, such as the bill before you, which offers a means to improve the current hodgepodge and confusing regulatory decision-making processes utilized by our Federal government to determine certain risks to the health and safety of our people deserves the attention of the Congress.

This subcommittee, along with other committees of the Congress and our Courts, have struggled for years for an answer to the question as to whether or not a substance at any given level, such as the food additives like saccharin or sodium nitrite; or a pesticide utilized on food crops; or a substance in the air resulting from utilizing gasoline in automobiles, presents a risk to human health.

In an area of great concern to me, Congress itself has enacted laws over the past seventy-five years to ensure the integrity of the Nation's food supply. Among these measures is the Food, Drug and Cosmetic Act, which includes the famous "Delaney Clause." This clause, designed to prohibit the addition of any cancer-causing substance to foods, has caused increasing consternation to scientists, regulators, the food industry, and the public in recent years, simply because it is so absolute in its treatment of risks. I'm sure everyone is familiar with its content but let me repeat it for the record -- "That no additive shall be deemed to be safe if it is found to induce cancer when

ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the food additives, to induce cancer in man or animals." When this clause was enacted in 1958, it was a perfectly logical mandate because scientific knowledge in these matters, and especially our ability to measure substances in very, very small amounts, was in a stage of relative infancy. Today, however, we have increased our capability tremendously, thanks to science, to measure particles of substance by one million times over our capability at the time the "Delaney Clause" was enacted. Moreover, we have learned more about the benefits of substances and the risks of not using certain substances. Additionally, we have learned that, as we increase our ability to detect these very small particles, they occur naturally in varying amounts in food products. All this is important because the "Delaney Clause," as it is currently written in the law, states rather emphatically that you can tolerate no-risk in allowing any additive to our food supply, if that additive shows in a test to cause cancer in any specie of animal. This has been interpreted by Federal regulators and some scientists to mean that you can feed substances suspected of causing cancer to cancer-prone test animals at huge daily amounts, way above the amounts consumed by humans, and if cancer results then the "Delaney Clause" applies. It has also been interpreted by many of our regulators that this test takes precedence over contrary tests in other species of animals. This clause has therefore established the zero risk theory. If this theory continues to dominate risk assessment with respect to safety of our food supply, do we have to ban all additives to food that show even the smallest trace of a suspected cancer risk?

Let us examine this zero risk theory a bit closer. First, can we apply the zero risk theory in practice? Second, have we established a system that realistically measures a true risk to man's health? Third, is there a degree

of risk to man's health that man is willing to accept? Fourth, is this system uniformly practiced with respect to food safety?

First, there are literally thousands of substances that make up our food supply. Some of these are combined in food processing or are mixed with other substances and are not, in the generally accepted sense, additives. Let's take potato hash for example. Potatoes, when naturally grown, contain a chemical substance which is suspected of causing cancer in animals. Corned beef, the other part of the mixture, contains sodium nitrite, an additive that some recently attempted to prove caused cancer in test rats. Even if we assumed that sodium nitrite added to corned beef didn't cause cancer, can we add naturally grown potatoes to corned beef to creat potato hash under the "Delaney Clause?" We also have a similar problem with Vitamin D_1, as it is also a suspected cancer-causing substance. Vitamin D_1 occurs naturally in wheat from the sun and through the cow into milk. Yet we add it to both bread and milk to improve the health of our children. What is the risk here, and to what degree is it a risk?

Second, how do we measure this risk? Is one additive more a risk than another? Do we have to place saccharin as a risk on a higher scale than we do Vitamin D_1? Is there an insignificant risk in a substance used as a food additive? The Supreme Court, in recently ruling in the benzene case, seemed to say that a risk must be found to be a significant risk to health before the Occupational Safety and Health Administration could up its standards of safety. Now I hasten to say, I find a difference between safety in the food supply and safety in the workplace, and I believe we should be far stricter with our food supply than with our concerns about safety in the workplace. But don't we have to arrive at risk assessment on a singular basis? This question certainly implies that there are degrees of risk.

Man has over the years accepted degrees of risk. Certainly, we all accept them every day. We ride airplanes, we ride in automobiles, and some ride bucking broncos. All have varying degrees of risk.

Finally, even within the Food and Drug Administration in the application of the "Delaney Clause," we find that we do not uniformly apply the law. The Agency has been ready to ban saccharin and nitrites in recent years, but it hasn't made a peep about Vitamin D_1 and black pepper and many other similar substances. Why? All have been on the cancer-causing suspects lists. Is it because of degrees of risk or acceptability of risk? Or is it because they are political hot potatoes?

What I have tried to indicate, Mr. Chairman, is that we need to examine thoroughly our methodology for achieving socially and scientifically acceptable risk analysis for risk comparison. We must make a coordinated effort among the Federal regulatory agencies and our scientific community to help improve this tool of regulatory decision-making. Otherwise we will continue the confusion that exists today over whether our food supply, the air we breathe, and our workplace are safe and, if not, how we logically and reasonably make them safe.

It is for the above reasons I support Congressman Ritter's bill and the good work of this subcommittee.

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Mr. WALGREN. The next witness I do want to call now in view of his schedule is James C. Miller, Counsel to the Vice President relating to the Presidential Regulatory Task Force. He is accompanied by Dr. Denis Prager, who is the Assistant Director of the Office of Science and Technology Policy.

Mr. Miller is Executive Director of the Presidential Task Force or Regulatory Relief and has been confirmed by the Senate this week to become Chairman of the Federal Trade Commission. We want to congratulate you on that confirmation and welcome you to the committee.

[A biographical sketch of Mr. Miller follows:]

JAMES C. MILLER III

James C. Miller III assumed the chairmanship of the Federal Trade Commission on October 5, 1981. President Reagan nominated Miller to a seven-year term as a member of the Federal Trade Commission on July 16, 1981. Upon confirmation by the Senate on September 21, 1981, the President designated Miller as Chairman of the FTC.

From January 21, 1981, to October 1981, Miller was Administrator for Information and Regulatory Affairs at the Office of Management and Budget. He also served as Executive Director of the Presidential Task Force on Regulatory Relief, chaired by Vice President George Bush.

After completing requirements for a doctorate in 1969, Miller taught for a year at Georgia State University in Atlanta.

From 1969 to 1972, he was a senior staff economist at the U.S. Department of Transportation (DOT). During 1972, he served as a research associate at the Brookings Institution and at the American Enterprise Institute for Public Policy Research (AEI). From September 1972 until June 1974, Miller was an associate professor of economics at Texas A&M University; while at Texas A&M, he served as a consultant to DOT and the National Bureau of Standards.

From July 1974 until October 1975, Miller served as a senior staff economist with the U.S. Council of Economic Advisers, where he specialized in matters relating to transportation, regulation and antitrust policy. During 1975, he became an AEI adjunct scholar. In October 1975, Miller was appointed the U.S. Council on Wage and Price Stability's assistant director for Government Operations and Research, with responsibility for the agency's public-sector monitoring functions; there he also served as a member of President Ford's Domestic Council Regulatory Review Group, which directed the Administration's program in regulatory reform.

Miller was a resident scholar and Co-Director of AEI's Center for the Study of Government Regulation from January 1977 until January 1981. He has served as a member of the Board of Editors of AEI's journal, *Regulation*, and on the Board of Editorial Advisers of *The AEI Economist*.

Miller was born in Atlanta and raised in Conyers, Ga. He received a B.B.A. in Economics from the University of Georgia in 1964 and a Ph.D. in Economics from the University of Virginia in 1969.

Miller is an elected member of the Executive Committee of the Southern Economic Association and also holds memberships in the American Association for the Advancement of Science, the American Economic Association, the Public Choice Society and the Western Economic Association.

Miller is the author of a number of professional articles and has co-authored or edited five books: *Why the Draft: The Case for a Volunteer Army* (Penguin, 1968); *Economic Regulation of Domestic Air Transport: Theory and Policy* (Brookings, 1974); *Perspectives on Federal Transportation Policy* (American Enterprise Institute, 1975); *Benefit-Cost Analyses of Social Regulation* (American Enterprise Institute, 1979) and *Reforming Regulation* (American Enterprise Institute, 1980).

Miller is married and resides with his wife and three children in Washington, D.C.

September 1981

STATEMENT OF JAMES C. MILLER III, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, AND EXECUTIVE DIRECTOR, PRESIDENTIAL TASK FORCE ON REGULATORY RELIEF, ACCOMPANIED BY THOMAS HOPKINS, DEPUTY ADMINISTRATOR FOR REGULATORY AND STATISTICAL POLICY; AND DR. DENIS PRAGER, ASSISTANT DIRECTOR FOR SCIENCE AND TECHNOLOGY POLICY, OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Mr. MILLER. Thank you, Mr. Chairman.

I am pleased to be here as one of my last official acts as Administrator for Information and Regulatory Affairs at OMB and as Executive Director of the Presidential Task Force on Regulatory Relief, which, as you know, is headed by the Vice President.

Joining me today on my left is one of my deputies, Thomas Hopkins, and to my right is Denis Prager, who is Assistant Director for Science and Technology Policy in the Office of Science and Technology Policy in the White House.

I do not have a prepared statement, Mr. Chairman, but I would like to make a few remarks. And then I would be glad to respond to any questions you or your colleagues might have.

As you know, Mr. Chairman, the President has given keen emphasis to the problems of regulation, the problems of excessive regulation, of insufficient regulation, but primarily excessively costly regulation. The President believes that in order for the economy to move forward, for the U.S. economy to grow, for the pie to grow larger, for there to be rising incomes for all Americans, we not only need tax relief and budget reductions and stable monetary policy, but we need regulatory relief. The Vice President is in charge of a Cabinet-level task force, which will achieve these ends.

On the 17th of February, President Reagan issued an Executive order which, among other things, tells agencies that within the scope of their existing statutes, they should promulgate regulations on the basis of adequate information about the effects of those regulations. They should also consider alternatives to the regulation. They should also consider the question of whether the benefits of the regulation exceed the costs, and they should order their priorities on the basis of net benefits.

Congressman Ritter has been a leader in identifying the need for analysis on the benefit side. Many of the regulations have as their purpose reducing risk to the American public. In order to determine what the benefits of a regulation would be, we must do risk assessment. That is key.

I share Congressman Ritter's concern over the quality of the risk assessment that is taking place in the Federal Government today. This has led us, Mr. Chairman, those of us involved in the work of the task force, to work very closely with Jay Keyworth, the President's Science Advisor, and with the Office of Science and Technology Policy. Tom Hopkins, who is in charge of analyzing and assessing the adequacy of analyses performed by regulatory agencies has worked closely with Mr. Prager and his colleagues.

I want to indicate to you, sir, that my successor in the job, Dr. Chris DeMuth, is likewise committed to making sure that risk assessment is done, where appropriate, and performed well.

We believe strongly that to serve the American public Government has to perform adequate analyses. We shouldn't make decisions in the dark, though perhaps we do too often. In order to accomplish that, people in the regulatory agencies have to be impressed at every turn the need to know the ramifications of their policies. This, sir, I submit, is the emphasis and thrust of administration in this area, and I am sure the President, the Vice President, Dave Stockman and others will not abide before securing this objective.

Thank you, sir.

Mr. WALGREN. Thank you very much.

I would like to recognize Mr. Gregg.

Mr. GREGG. I have no questions at this time.

Mr. WALGREN. Mr. Skeen?

Mr. SKEEN. No questions.

Mr. WALGREN. Mr. Ritter?

Mr. RITTER. The bill attempts, in part, to seek some kind of coordinative role outside of each individual agency, not a super agency for risk assessment by any means, but somebody or some group or some area of responsibility that sees to it that those agencies that would be involved in these kinds of procedures actively pursue their own interested ramifications of risk assessment, risk comparison, and putting hazard in perspective.

Could you comment on that?

Mr. MILLER. Congressman, I think there is a keen need for that. I think for one thing agencies should share with each other what they have learned. I think there needs to be some consistency and approach to regulatory issues across agencies. We are in the process of securing that objective.

I think, sir, though, that the Presidential Task Force on Regulatory Relief is the appropriate vehicle for achieving that end.

Mr. RITTER. Thank you. I would tend to agree with you on that.

Would OSTP have some role in this in working with the Regulatory Relief Task Force?

Mr. MILLER. Absolutely.

Mr. RITTER. In that OSTP would conceivably be looking after the intellectual quality, the scientific quality of some of the regulatory agency efforts in this regard.

Mr. MILLER. That's right. There is no question but that there is a need for peer review—this is for review of what agencies have done.

Let me just tell you they are on two levels.

First, is the involvement of OSTP in of aiding Tom Hopkins, my deputy, and my other staff members who are reviewing these regulations and offering advice on questions of scientific import.

Second, from time to time OSTP is called upon by agencies themselves to give advice.

Third, Dr. Keyworth has indicated his keen interest in establishing as a high priority the review of agencies' processes of assessing the scientific data which in many instances form the bases of the regulations that are needed.

We have not brought that program to fruition as of yet. It is in the implementation stage. We have recognized the need for it for some time, and have begun to move forward on it.

Mr. RITTER. I have no further questions for Dr. Miller.

Mr. WALGREN. Mr. Martin, would you like to join in?

Mr. MARTIN. I am just here as a guest, Mr. Chairman, so I'll just listen in.

Mr. MILLER. Could I just add something, sir? The point that Congressman Martin made about risk and comparative risk is so important, I think it behooves us as a Nation to consider the ramifications of reducing a risk both in terms of the benefits and the costs of reducing that risk. We shouldn't have a knee-jerk reaction to a substance. We really need to think through this very carefully. Congressman Martin has talked about this and has written about it, and I applaud the points he has raised and agree with him entirely.

Mr. WALGREN. If we were able to authorize these levels of funding, would OMB be up here on the Hill supporting an appropriation of $1.5 million to the regulatory group?

Mr. MILLER. I am reluctant to give any kind of hard and fast answer to you on that, sir. I think, though, our position, the position of OMB and the administration, would be that we should accomplish that end under given funding. In other words, we would not be in favor of additional expenditures of moneys of this purpose.

We share the committee's concerns; we share the concerns that are driving Congressman Ritter's legislation. We hope to achieve those goals under the present structure.

One thing that I hope has characterized our efforts for regulatory relief is that we have been both mean and lean. In terms of precedent, I think that is very important for any agency or any initiative by the Government. I would be reluctant to ask for additional funds. I think we can accomplish the goal with what we have.

Mr. RITTER. I would like to just comment on that, Mr. Chairman.

I would like to thank the current Director, and since that group was his own group, I think that is a meaningful statement that he has made, that he is willing to accomplish the goals of this legislation within their existing budget framework. I would hope that he would convey those ideas and recommendations to Mr. Chris DeMuth, who will be taking over in his stead.

Mr. MILLER. Yes, sir. We have discussed this and he shares that concept and goals.

Mr. RITTER. Thank you.

Mr. WALGREN. One of the specific goals of this legislation is to reduce to writing a framework within which these decisions could be analyzed and judged.

Is your office able to do that at this point?

Mr. MILLER. Well, we are working on that. Let me tell you another aspect of this.

I would anticipate that over the next months and certainly over the next couple of years the administration will be addressing to Congress the need for some changes, some adjustments, some improvements, in the underlying organic statutes in many of the

regulatory agencies. In that context, the administration will be recommending to Congress establishing a more rigorous framework for assessing the benefits and the costs of regulatory proposals. I would see that being built upon work that is now in the genesis stage of reviewing that Dr. Keyworth and his associates in conjunction with my office, is undertaking—that is, to review the agencies' present programs and what improvements need to be made in them.

Mr. WALGREN. Do you think this can be done in the context of the individual programs or the individual evaluations? It strikes me that, as I understand it, my own sense for the needs in this area is for some theoretical framework to be developed that would then allow us to look at individual cases. And if it comes up in the framework of every individual case, you won't get the consensus and objectivity that I understand the bill to pursue.

Mr. MILLER. Right. What we are trying to do, Congressman, is to look at what would be ideal, and we are going to be asking agencies to do that within the scope of the law.

Now, in some cases they may simply not be able to do it. It's like the case situation with report to regulatory input analyses. In some cases, some of the things that are asked for in the regulatory analysis by law are irrelevant or are not particularly pertinent. But we're going to ask the agencies within the framework of existing law that they perform the analysis anyway. And where existing law restrains agencies from doing appropriate risk assessment, we will be asking the Congress to make modifications in those laws. That is my prediction.

Mr. WALGREN. So it is your view that this can be done somewhat on a case-by-case basis? My concept of this particular bill and support of the goals of this bill would be to make an effort that may be more theoretical than the individual case, and what concerns me is that apparently that has not been able to be done yet within the administration and you, from your experience in the office you just left, feel that we ought to do this on an individual basis as we see the laws restraining the proper risk being able to be taken into account.

Mr. MILLER. There have been some improvements in the risk assessments the agencies have done pursuant to the President's requirement for regulatory impact analysis. We need further improvements, and we are going to secure those.

We have talked with the heads of agencies like Ann Gorsuch, the head of EPA and others, about improvement of the scientific basis for their decisionmaking, the need for peer review, the need for more thorough study and review of what they're doing. That is what we have underway.

I think what we ought to do is achieve whatever improvements we can under existing law, and then ask for changes in the laws to allow regulations to be implemented on the basis of such better information.

As I understand it, sir, the legislation before this committee is really one of having the executive branch first study the risk assessment procedures practiced by the agencies and then doing a better job of coordinating these efforts.

Now, I think basically these goals can be achieved under the present setup by the Presidential task force. We, I think, have made a good start in achieving that goal. Beyond that, though, is the question raised by Congressman Ritter or Congressman Martin to the effect that we need to make sure that agencies have the requisite flexibility to make decisions on the basis of what that information shows. In some cases they do not.

Mr. WALGREN. I see.

Mr. RITTER. I would just like to add, Mr. Chairman, one query. The legislation calls for a summary report that would then be distributed to the public as well. That report will take some reasonable amount of resources. But you again feel that is within the resources of your existing staff to handle, and that perhaps you are engaged in some of that activity already; is that your response?

Mr. MILLER. Yes; it is. I do not anticipate a report within the next few months, but within the timeframe of 1 year or less I think such a report could be forthcoming.

Mr. RITTER. Well, the legislation before us calls for a report to summarize the findings of the test cases within the individual agencies, and what I hear you saying is that your group has the resources to carry out the requisites of this legislation.

Mr. MILLER. Yes, sir, I believe so. If we do not have them in-house, we will conscript them elsewhere.

Mr. RITTER. Thank you.

Mr. WALGREN. Could I ask at that point, then, it seems to me important that the administration be behind this bill.

Mr. MILLER. Yes.

Mr. WALGREN. I think it would be fair to say that we're not going to break much new ground in this Congress if the administration is not behind it. Therefore, it becomes important that the administration represent to the committee, in very direct terms, its view of its support for this bill.

In that context, I wonder whether we could ask your successor in this office, inasmuch as you have indicated that your approach to the office was that there were the resources available to accomplish the specific tasks and goals in this bill, I would appreciate it very much and I think it important for this legislation to move forward, if the administration would submit to us a formal statement of support for the particular goals in the bill and an evaluation or statement that they do, in fact, believe that the resources necessary to carry out these goals are justified in putting in place at this point, and that either there are resources that could be pulled from present personnel and present efforts, or I would think along with that you would have to have some kind of estimate of what you feel accomplishing these goals would take in terms of a personnel commitment.

I don't mean to be too specific, but I think it is important that we know the administration does support this and is willing to do what is necessary.

Mr. MILLER. Mr. Chairman, let me amplify and recapitulate here and perhaps clarify my own view at this point.

The first is, we share the goals of this bill—very much so—and second, I have indicated I don't think appropriations are necessary. I think we can achieve them with given resources.

The third point is, though, with respect to the bill itself, I think the President's Executive order requires agencies to achieve many of the goals that are characterized in this bill. In terms of the way that would be achieved, I think we have already, within the task force on regulatory relief, many of the processes outlined in the bill, or something suitable or substitutable. So the question of the administration's support for the legislation I think is a very open question. I am at this point not authorized to support the legislation.

Mr. WALGREN. Yes; I understand.

Mr. MILLER. In fact, my feeling is the bill would be redundant in a real way, and for that reason I think the administration would not be in favor of the legislation's passing.

Mr. WALGREN. I perfectly appreciate the position you are in and I would not ask you to go beyond what you can accurately represent what the administration's view is. But as I hear your testimony, you are saying essentially that, as is proper, that the administration has sensed a need in this area just as the Members of the Congress have sensed a need in this area——

Mr. MILLER. Right.

Mr. WALGREN [continuing]. And that you have established the regulatory task force which is operating in this area.

I guess what I would like to see from the administration is a detailed statement from the regulatory task force, since they are the ones that you view as being able to break the ground that this bill is designed to break, a detailed statement from the regulatory task force as to how they are going to cover the ground that this bill covers. And then I think with that we would be able to see the measure of support that comes from the administration.

Mr. RITTER. I would like to ask Dr. Miller—you have stated that you feel this bill would be redundant to efforts already taking place and, therefore, the administration would not support the actual bill itself; is that correct?

Mr. MILLER. That is my inclination. I am not——

Mr. RITTER. Let me just say there are some major changes underway in the way we view regulation and the basis upon which regulation is made. I believe those changes should involve not only the new administration and executive branch but also the Congress.

I think this is important because the Congress insures that the grassroots, back-home people, American communities all over this country, have a reasonable say in this issue as well. If we are truly seeking to reform the regulatory directions, I submit to you that it is extremely important to have the Congress be a part of this effort and not to simply do it from the top down.

I would urge you, with that in mind, to consider what the chairman has asked for, and that is, a rather detailed review with your staff of the principles, your comments—and we haven't entered a markup stage and your input I think would be very valuable to that process. But I would urge you to withhold your judgments as to redundancy and consider the need to have Congress, as well as the executive branch, play a role in this process of regulatory reform.

Mr. MILLER. Well, your point is well taken, Congressman. I will be glad to respond to the chairman's request for a more detailed outline of the kinds of things that we anticipate achieving——

Mr. RITTER. I can tell you, if I might interrupt, the previous administration basically came down against the concept. A future administration could do the same. Therefore, it is important that Congress have its own momentum, its own activities in this area. I hope you would consider that.

Mr. MILLER. Right.

One thing, Congressman Ritter, the thing in this area that is the most restraining I think is the organic statutes themselves. I think working with the Congress to modify the organic statutes and the same time the President working through his administration to improve executive branch agency decisionmaking, will get us a long way down the road to improved regulations.

Mr. RITTER. I understand what you're saying, and of course, we are going through this process at this very time. I personally am in the middle of Clean Air Act deliberations that have a great deal to do with what you are saying.

But the Science and Technology Committee's contribution here—and it is probably one of the most bipartisan committees I have experienced and have seen here in the Congress—their contribution can set a kind of basic level of intelligence for this area. I think what the Science and Technology Committee does in this area, because of its often bipartisan nature, can be very well respected by other Members of Congress who, indeed, have to be voting and have to be considering the organic statutes that are perhaps in need of reform.

But I would not downplay the ability of the Science and Technology Committee to have a kind of generic effect on Congress' view in issues that concern this very subject—whether it is the Clean Air Act or whether it is energy issues or food and drug issues, which we will be considering generic features—I really believe that this committee and what it says in a more bipartisan and more basic intellectual sense could be respected by the Congress and help in the process of regulatory reform.

Mr. WALGREN. Thank you very much. We appreciate that we have invaded your time beyond your next appointment, so thank you very much.

Mr. MILLER. Thank you, sir.

Mr. WALGREN. The record will remain open until October 16 for the submission we talked about.

[The information follows:]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 16, 1981

OCT 19 1981

Honorable Doug Walgren, Chairman
Subcommittee on Science, Research
and Technology
Committee on Science and
Technology
House of Representatives
Washington, D.C 20515

Dear Chairman Walgren:

I am pleased to provide this statement in response to the request you made to my predecessor, James C. Miller III, during the September 24 hearing of the Subcommittee on Science, Research and Technology. As Mr. Miller emphasized in his presentation before your Subcommittee, this office is deeply committed to the goals which underlie H.R. 3441. The proposed legislation addresses a critical issue in efforts to improve regulatory decision-making--the identification and assessment of health, safety, and environmental risk. We believe, however, that existing administrative efforts are the most appropriate means of furthering the use of risk analysis and improved scientific information in the regulatory process, and that specially funded legislation such as H.R. 3441 is unnecessary at this time.

President Reagan is committed to a disciplined examination of the regulatory process that will result in more effective and reasonable regulations. As one of his first acts in office, the President formed the Presidential Task Force on Regulatory Relief and designated Vice President Bush as its Chairman. The members of the Task Force are the Secretaries of the Treasury, Commerce, and Labor, the Attorney General, the Director of the Office of Management and Budget, the Assistant to the President for Policy Development, the Chairman of the Council of Economic Advisers, and the Director of the Office of Science and Technology Policy. The Task Force has ongoing responsibilities for reviewing major regulatory programs of the Executive Branch agencies, overseeing the development of legislative proposals required by Congressional mandates, and making recommendations to the President on how to reform the federal regulatory process.

In addition to creating the Task Force, on February 17, 1981, the President signed Executive Order 12291, which was designed to improve the coordination and management of the Federal regulatory process. It is administered by the Office

of Management and Budget under the overall direction of the Task Force. Under the Executive Order, all agencies, to the extent permitted by law, are asked to adhere to the following five requirements in promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation:

1. Regulatory decisions shall be based on adequate information concerning the need for and consequences of proposed government action;

2. Regulatory action shall not be undertaken unless the potential benefits to society from the regulation outweigh the potential costs to society;

3. Regulatory objectives shall be chosen to maximize the net benefits to society;

4. Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and

5. Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Under the Executive Order, federal agencies are required to undertake thorough analyses of the risks addressed by their health, safety and environmental regulations. The Executive Order also requires each agency to prepare, and to the extent permitted by law to consider, a "regulatory impact analysis" (RIA) when major rules are proposed or reviewed. RIA's are to contain:

1. A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits;

2. A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs;

3. A determination of the potential net benefits of the rule, including an evaluation of effects that cannot be quantified in monetary terms;

4. A description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of this potential benefit and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted; and

5. An explanation, if necessary, of any legal reasons why the rule cannot be based on the five requirements set forth above to guide regulatory decison-making.

The Director of the Office of Management and Budget has used his authority under the Executive Order to issue uniform guidelines encouraging the use of risk-analysis methods. As the enclosed copy (Enclosure 1) of the interim RIA guidelines illustrates, risk-assessment techniques will be required in RIA preparation whenever these techniques will contribute to more informed regulatory decision-making. We intend to give RIAs careful examination on the use of these techniques, with particular attention to risk assessment.

Our efforts to use the best available scientific data to support regulatory decision-making will be greatly assisted by the recent addition of Dr. George A. Keyworth, II, the President's Science Advisor, to the Presidential Task Force on Regulatory Relief. The Vice President has also announced the formation of a Regulatory Work Group on Science and Technology, which will be chaired by Dr. Keyworth and function under the direction of the Task Force (see Enclosure 2). Members of the Work Group are Anne Gorsuch, Administrator of the Environmental Protection Agency; Arthur Hayes, Commissioner of the Food and Drug Administration; Nancy Steorts, Chairman of the Consumer Products Safety Commission; and C. W. McMillan, Assistant Secretary for Marketing and Inspection of the Department of Agriculture.

The Work Group will provide an important mechanism for the regulatory agencies, to coordinate and share their scientific and analytical skills. Group members will work on improving the quality of the scientific data collected on the environmental, health, and safety effects of potentially hazardous exposures; enhancing agency scientific and analytical capabilities; and increasing the participation of qualified scientists in the peer review of data, data analysis, risk estimates, and exposure level recommendations used on a basis for regulatory decisions. One of the Group's top priorities will be the more systematic and informed use of the techniques of risk assessment, risk evaluation, and comparative risk analysis.

In addition to these activities, I should mention that the National Science Foundation, with the help of the National Academy of Sciences, has undertaken a research program to develop methodologies of risk assessment and risk management.

We expect these efforts to improve the regulatory decision process greatly, and believe that much of what H.R. 3441 embodies can be accomplished through them. Most important, we expect these efforts to bring improved risk analysis to bear directly at the level where it counts the most--in the regulatory agencies themselves.

The efforts of the Task Force to use risk analysis techniques will yield valuable information. Consideration of specific legislation should wait until we can use this information to make more informed judgements about whether legislation is necessary. We believe that any legislation now should simply endorse the principles behind risk analysis, without a specially funded agenda such as that in H.R. 3441; the Congress is currently considering regulatory reform legislation (S. 1080, H.R. 746) which contains such an endorsement.

Risk analysis is an important tool in informed regulatory decision-making, and I hope that you and your colleagues will continue to focus attention on the need for improved

risk-analysis methods. While the Administration cannot support H.R. 3441 at the present time, we are deeply committed to its ultimate goals--and we applaud the diligent work both of yourself and the bill's author, Congressman Don Ritter, toward strengthening the role of objective scientific knowledge in the regulatory process.

Sincerely,

Christopher DeMuth
Administrator for Information
and Regulatory Affairs

c: Honorable Don Ritter

Enclosures

ATTACHMENT A

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

June 12, 1981

INTERIM REGULATORY IMPACT ANALYSIS GUIDANCE

A Regulatory Impact Analysis (RIA) should demonstrate that a proposed regulatory action satisfies the requirements of Section 2 of Executive Order 12291. To do so, it should show that:

- There is adequate information concerning the need for and consequences of the proposed action;
- The potential benefits to society outweigh the potential costs; and
- Of all the alternative approaches to the given regulatory objective, the proposed action will maximize net benefits to society.

The fundamental test of a satisfactory RIA is whether it enables independent reviewers to make an informed judgment that the objectives of E.O. 12291 are satisfied. An RIA that includes all the elements described below is likely to fulfill this requirement. Although variations consistent with the spirit and intent of the Executive Order may be warranted for some proposed or existing rules, most RIAs are expected to include these elements.

This document is written primarily in terms of proposed regulatory changes. However, it is equally applicable to the review of existing regulations. In the latter case, the impact of the regulation under review should be compared to a baseline case of no regulation and to reasonable alternatives.

Elements of a Regulatory Impact Analysis

Preliminary and final Regulatory Impact Analyses of major rules should contain five elements.

(1) Statement of need for and consequences of the proposal.

The statement of the need for and consequences of the proposed regulatory change should address the following questions:

(a) What precisely is the problem that needs to be corrected? (That is, what market imperfection(s) give(s) rise to the regulatory proposal? Causes, not just symptoms, should be identified.)

(b) How would the regulatory proposal, if promulgated, improve the functioning of the market, or otherwise meet the regulatory objective(s)? Since regulatory failure may be a real possibility, is it clear that the proposed regulation would produce better results than no regulatory change? (Imperfectly functioning markets should not be compared with idealized, perfectly functioning regulatory programs.)

(2) An examination of alternative approaches.

The RIA should show that the agency has considered the most important alternative approaches to the problem and must provide the agency's reasoning for selecting the proposed regulatory change over such alternatives. Although only the most promising alternatives need be evaluated at length, the agency should consider:

(a) The consequences of having no regulation. (Are there existing or potential market, or judicial, or state or local regulatory, mechanisms that could resolve the problem? For example, RIAs for health and safety regulations should consider the adequacy of tort law or state programs such as workmen's compensation.)

(b) The major alternatives (if any) that might lie beyond the scope of the specific legislative provision under which the proposed regulation is being promulgated. (This may require a broad comparison across programs, including those both within and outside the jurisdiction of the issuing agency.)

(c) Alternatives within the scope of the specific legislative provision. These include:

(i) Alternative stringency levels;

(ii) Alternative effective dates; and

(iii) Alternative methods of ensuring compliance.

(d) Alternative, market-oriented ways of regulating (whether or not they are explicitly authorized in the agency's legislative mandate), including:

(i) Information or labeling (to enable consumers or workers to evaluate hazards themselves);

ii) Performance rather than design standards; and

(iii) Economic incentives, such as fees or charges, marketable permits or offsets, changes in insurance provisions, or changes in property rights.

(3) Analysis of benefits and costs.

(a) Benefit estimates:

The RIA should state the beneficial effects of the proposed regulatory change and its principal alternatives. It should include estimates of the present value of all potential real incremental benefits to society. Benefits that can be estimated in monetary terms should be expressed in constant dollars. Other favorable effects should be described in detail and quantified where possible. An annual discount rate of 10 percent should be used; however, where it appears desirable, other discount rates also may be used to test the sensitivity of the results. Assumptions should be stated, and the RIA should identify the data or studies on which the analysis is based.

There should be an explanation of the mechanism by which the proposed action is expected to yield the anticipated benefits.

A schedule of benefits should be included that would show the type of benefit, to whom it would accrue, and when it would accrue. The numbers in this table should be expressed in constant dollar terms.

(b) Cost estimates:

The analysis should include estimates of the present value of all the real incremental costs of the proposed regulatory change and its principal alternatives (i.e., the costs that would be incurred by society as a result of taking the proposed action or an alternative). All costs that can be estimated in monetary terms should be expressed in constant dollars. Other costs should be

described completely and quantified where possible. An annual discount rate of 10 percent should be used; however, where it appears desirable, other discount rates also may be used to test the sensitivity of the results.

To support the present value estimates, a schedule of costs should be included that would identify the type of cost (capital, recurring, etc.), who would bear that cost, and when that cost would be incurred. The numbers in this table should be expressed in constant dollar terms. Assumptions should be stated, and the RIA should identify the data or studies on which the analysis is based.

Where possible, various adverse effects of the regulation -- such as those from reductions in competition, innovative activity, or productivity growth -- should also be identified.

Transfer payments from one group to another, such as taxes and insurance premiums, should not be included in the calculation of real resource costs, but they nevertheless should be identified. Any major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions also should be identified.

(c) Net benefit estimates:

The monetary social cost should be subtracted from the monetary social benefit to obtain the monetary net benefit estimate (which could be negative). Any remaining nonmonetary but quantifiable benefit and cost information also should be presented. Then, nonquantifiable benefits and costs should be listed, in a way that facilitates making an informed final decision. Where many benefits are not easily quantified, the results should show the cost-effectiveness of the several alternatives. When there are major uncertainties affecting the assumptions or the methodology, the most likely or best estimates should be used, but reasonable alternative assumptions also should be examined to test the sensitivity of the results to changes in assumptions. The results should be arrayed so that the policymaker can easily see the effects of the different assumptions.

(4) Rationale for choosing the proposed regulatory action.

The RIA should include an explanation of the reasons for choosing the selected regulation. Ordinarily the regulatory alternative selected should be the one that achieves the greatest net benefits. If legal constraints prevent this choice, they should be identified and explained, and their net cost should be estimated.

(5) Statutory Authority

The RIA should include a statement of determination and explanation that the proposed regulatory action is within the agency's statutory authority.

PRESS RELEASE

ENCLOSURE 2

THE VICE PRESIDENT
OFFICE OF THE PRESS SECRETARY

FOR IMMEDIATE RELEASE
Friday, October 9, 1981

CONTACT: Peter Teeley
Shirley Green
(202) 456-6772

Vice President George Bush announced today that Dr. George A. Keyworth, II, Director of the Office of Science and Technology Policy, has been made a member of the Presidential Task Force on Regulatory Relief.

The Vice President also announced the formation of a Regulatory Work Group on Science and Technology, which will be chaired by Dr. Keyworth and will function under the direction of the Task Force. Members of the Work Group are Anne M. Gorsuch; Administrator of the Environmental Protection Agency; Arthur Hull Hayes, Jr., Commissioner of the Food and Drug Administration; Nancy Harvey Steorts, Chairman of the Consumer Product Safety Commission; Thorne Auchter, Assistant Secretary of Labor for Occupational Safety and Health; and C. W. McMillan, Assistant Secretary of Agriculture for Marketing and Inspection.

The purpose of the Work Group is to strengthen the role of scientific data and analysis in the regulatory process. Science has come to play an increasingly important role in environmental, health, and safety regulation in recent years. As a part of the Task Force's effort to improve the regulatory process, the Work Group will examine ways in which the agencies which have primary responsibility for these areas can work together to enhance the scientific basis of their regulatory decisions. The Work Group will place particular emphasis on developing and applying techniques for quantifying and comparing risks of hazardous exposures.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 16, 1981

Honorable Don Ritter
124 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Ritter:

I hope the enclosed letter to Chairman Walgren will clear up any misunderstanding concerning the Administration's support for your efforts to strengthen the role of risk assessment in regulatory decision-making. As you and I have discussed, the Administration cannot at this time support legislation, such as H.R. 3441, which provides for new expenditures. At the same time, we believe that objective scientific assessment of health, safety, and environmental risk is an essential component of sound regulatory policy--one which has been given far too little attention in the past. The Administration is greatly indebted to you for emphasizing the need for objective risk assessment in regulatory policy, particularly for the comparison of the risks addressed by regulatory programs and those faced by individuals in daily life.

We are looking forward to working closely with you on this critical aspect of the President's regulatory relief efforts. I know that Dr. George Keyworth, the President's Science Advisor and Chairman of the Regulatory Work Group on Science and Technology, is greatly interested in your special knowledge and experience in this area and will keep you closely informed of the Work Group's efforts.

Cordially,

Christopher DeMuth
Administrator for Information
and Regulatory Affairs

Enclosure

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICE OF
THE CHAIRMAN

November 24, 1981

Honorable Doug Walgren
Chairman
Subcommittee on Science,
Research and Technology
Committee on Science and
Technology
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Walgren:

Thank you very much for your letter of October 22nd, enclosing a copy of the transcript from my presentation before your Subcommittee last September.

Enclosed are my corrections on the transcript. I apologize for the delay, but the change of jobs has prevented my giving attention to the matter sooner.

Also, I just wanted to take this opportunity to commend your Subcommittee for holding the hearings on Congressman Ritter's bill. As you may know, Congressman Ritter discussed with me and other Administration officials on several occasions the need to improve risk evaluation, and through his leadership the Presidential Task Force on Regulatory Relief took significant steps to implement some of the procedures outlined in his bill. Frankly, had it not been for Congressman Ritter's insistence on this matter we might have been negligent in addressing what your hearings so clearly identified as a problem of major import.

Although I am no longer officially part of the Task Force headed by the Vice President, I remain vitally interested in efforts to improve the government's risk assessment capabilities. If I can ever be of service to the Subcommittee in that regard, please do not hesitate to let me know.

Sincerely yours,

James C. Miller III
Chairman

Enclosure
c: Congressman Don Ritter

Mr. WALGREN. The next witness is Michael Baram. Mr. Baram is an attorney specializing in regulatory law. He is a professor of law and director of a program at the Boston University School of Law that focuses on law and technology.

We appreciate your being able to come and look forward to your statement.

[The biographical sketch of Mr. Baram follows:]

Michael S. Baram --- Biographical Sketch (1981)

Michael S. Baram is an attorney specializing in regulatory law and other law applicable to the management of risks to health, safety and environment. He is a partner in the law firm of Bracken and Baram, Boston; Professor of Law and Director of the Program on Government Regulation at the Franklin Pierce Law Center; and Adjunct Professor of Engineering and Public Policy at Carnegie-Mellon University. In 1981, he will move from Franklin Pierce Law Center to Boston University School of Law, where he will direct the Program on Law and Technology.

He has been a member of the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR Committee), the NAS Committee on Radioactive Waste Management, and the NAS Committee on Environmental Manpower. He is a member of the Environmental Protection Agency Administrator's Advisory Committee on Toxic Substances; and has served as a member of the Council of the Science and Technology Section of the American Bar Association; and as Chairman of the ABA's Environmental Law Committee, General Practice Section. He has also served as a member of the Advisory Committee on Construction Safety and Health of the Occupational Safety and Health Administration; and on other committees and panels dealing with risk management issues.

Mr. Baram has served as a consultant to the Administrative Conference of the United States, the U.S. Congress' Office of Technology Assessment, Brookhaven National Laboratory and several federal agencies, the United Nations World Health Organization, and the Organization for Economic Cooperation and Development.

He has conducted research on various risk management subjects and published extensively. Among recent publications and reports are the following:

- Alternative to Regulation for the Management of Risks to Health, Safety and Environment, 2 v. report sponsored by Ford Foundation and National Science Foundation (to be published by Lexington Books, D.C. Heath Co., June 1981).

- Regulation of Health, Safety and Environment and the Use of Cost-Benefit Analysis, report sponsored by the Administrative Conference of the United States and the National Science Foundation, with recommendations adopted by ACUS in June 1979. (Report published by ACUS in 1979, and in abbreviated form by the Ecology Law Quarterly, University of California, Berkeley, spring 1980).

- Legal Aspects of the National Flood Insurance Program: A Unique Approach to Risk Management, report to the Federal Emergency Management Agency (1980).

- The Legal Framework for Managing Carcinogenic Risk, report to the U.S. Congress, Office of Technology Assessment (1980).
- Legal and Institutional Aspects of Using Cost-Benefit Analysis to Control Ionizing Radiation, Ch. IV of National Academy of Sciences "BEIR-II" report (1977); and Harvard Journal of Legislation v. 14, n. 4 (June 1977).
- Marine Mining of the Continental Shelf: Legal, Environmental and Technical Considerations, Ballinger Press (1978) (based on NSF project).
- Environmental Law and the Siting of Facilities, Ballinger Press (1976).
- Numerous articles in legal, policy and scientific journals: e.g. "Technology Assessment and Social Control," Science, v. 180, n. 4085 (1973); and "Social Control of Science and Technology," Science, v. 172 (7 May 1971).

Mr. Baram received his B.S. degree from Tufts University (1957), and the L.L.B. (J.D.) degree from Columbia University (1960).

STATEMENT OF MICHAEL S. BARAM, ESQ., PARTNER, BRACKEN & BARAM, BOSTON, MASSACHUSETTS

Mr. BARAM. Thank you, Mr. Chairman.

Over the last few years I have directed several studies of risk management and regulatory reform. These included a study of the use of cost benefit analysis in the prior administration for dealing with health and safety issues, for the Administrative Conference of the United States; and studies for the Ford Foundation and the National Science Foundation, on alternatives to regulation for managing risks to health and safety.

My overall impression of this bill is that it is a very important step toward meeting an urgent need of the times, the need for improving public and private sector assessments of risk, for strengthening the quality and credibility of how we go about managing risk, whether through regulation or private means.

The bill also promotes developments which will make regulation of health and safety eventually more cost effective, more coordinated.

It is clear that the previous witness, Mr. Miller, has a completely different perspective on risk management. His perspective, of course, is that risk management is primarily a matter for economic analysis, to be done through the cost benefit process by those involved in regulatory relief in the agencies and the Executive Office. This has been the fate of risk management over the last several administrations, and what it has led to are ad hoc, hand-tailored analyses, essentially economic analyses, of technically uncertain areas. I submit that these efforts of predecessor OMB's, the earlier Council on Wage and Price Stability, and by the agencies to meet the demands of the Executive Office over the last several years have damaged the credibility of risk analysis, and have not promoted any coherent and effective approach toward risk management.

I think this bill goes a lot further. This bill is an attempt to really deal with risk in all of its dimensions and eventually, by better dealing with risk, to achieve more cost-effective Government. The approach of the new regulatory relief team and others now working under Executive Order 12291 consists once again of ad hoc economic analyses, not the standardized risk assessment approaches needed. So I think we have not had a meeting of the minds in the earlier discussion today, and this is important. The previous discussion confirms my belief that this bill should be enacted, because it is clear that risk management will not be dealt with adequately by the regulatory relief team and others now working under Executive Order 12291.

Let me give you my concept of risk management—it goes far beyond cost benefit analysis. It is based on my having looked at over 30 agencies that deal with health and safety issues, in a project for the Administrative Conference a few years ago to see how agencies dealt with technical uncertainty in managing risks. What I found was that several classic steps or functions had to be carried out by each agency in their management of risks by regulation.

First of all, an agency has to identify the risk and determine who is responsible for its management. Many times agencies prefer not to deal with a risk, and suggest that it is some other agency's problem because they don't have clear regulatory jurisdiction. So, the first step is identifying risk and clarifying who is responsible for its management.

The second step for the agency is verifying in a preliminary sense that the risk is worth addressing. After all, anyone may walk in off the street and confront an agency with alleged evidence that a substance is harmful. Before an agency launches into a massive and costly research effort, there has to be some way of preliminarily verifying whether or not the risk is imminent, and is otherwise one that the agency should address.

The third step for an agency is to set about measuring the risk, assessing it in terms of various dimensions—what are the potential impacts, when are they likely to occur and at what magnitude, how irreversible will the impacts be, what sectors of society will be affected—will it be the consumer sector, the worker sector, the environmental sector?

Obviously, agency practices differ. The differences in practice may be due to the agency's structure and traditions. Some have their own inhouse research laboratories; others turn to the National Academy of Sciences or some other organization for a quick study; others get in touch with colleagues in industry or other agencies. The practices will differ because of other factors as well: For example, the availability of good data, of proven analytic methods, of parallel developments in other agencies, and of course, the agency's statutory mandate and recent court decisions.

Thus, the very important step of trying to objectively measure risk may take many different directions, and this is a problem that needs serious congressional attention.

The fourth step which a few agencies engage in, has to do with establishing causation. What are the linkages between risk sources and effects or impacts? Can they be proven conclusively or not?

Clearly information as to causation can be very useful for designing effective regulatory strategies.

A fifth step involves a matter which regrettably only a few agencies engage in, and that is the assessment of what alternative means are available, in addition to rulemaking, for managing the risk. Most agencies limit their objectives to rulemaking—how to develop support for a rule and what the timing of the rulemaking should be.

I submit that there are several other means for dealing with many of these risks, such as private sector approaches, which in certain cases would be more cost effective and efficacious for managing the risk. But the agencies, in general, fail to consider these alternatives.

Under the new Executive Order 12291, and in light of various studies now available, the agencies are beginning to consider such alternatives in addition to rulemaking.

The sixth step has to do with the determination of the level of the level of risk reduction the agency wants to achieve. This is a very difficult, socio-economic, political, and value-laden issue. Unfortunately, the statutes that the agencies work under do not give them adequate guidance for this step, and this is a chronic problem.

The seventh and last step is reaching a decision, based on the foregoing findings. In my opinion, it should be limited to agency choice of the most cost effective approach to achieving the desired level of risk reduction. Whether that involves agency regulation or agency reliance on alternatives to regulation, the cost-effective criterion should determine. And I want to stress that cost-effectiveness differs from the cost-benefit approach.

These seven steps, whether followed completely or poorly in different agencies, constitute risk management.

Mr. WALGREN. May I ask—I missed one of the steps, apparently.

Mr. BARAM. Yes.

Mr. WALGREN. I have "should the agency get involved," and then I go to "measurement." Did you have anything between those?

Mr. BARAM. Yes; a second step of verifying that the risk is worth addressing. A number of agencies are beset by alleged evidence that comes in from various sectors, which is not of very good quality, and they don't know how to deal with this problem effectively, it seems.

Thus, I have this larger concept of risk management, larger than cost-benefit analysis, and it is based on a study of the functions of different agencies. I have set it out as seven different steps, in order to separate out the technical and fact-finding issues from the legal issues and the value-based issues. I have also tried to stress the need to somehow promote alternative ways of dealing with risk, other than just by rulemaking. This larger concept of risk management opens up alternative ways of achieving risk reduction. Therefore, risk management as an outcome of this bill can promote cost—effectiveness, objectivity, and regulatory reform—very important goals.

Risk management in our society must not become a cold-blooded, stochastic exercise of weighing portable cost to industry against arbitrary dollar values set for certain health impacts on various

sectors of society. Our society has traditionally fostered more qualitative ways of dealing with risks which lead to human illness and human health problems.

So I offer this larger conceptualization of risk management, and have submitted a prepared statement to that effect. From this larger view of the risk management problem and the enactment of this bill will come several benefits for the regulatory process. First of all, we will gain better knowledge of what the different agencies are doing and how we can better coordinate their activities.

Second, a comparative risk assessment approach will be fostered, and this is very important. Having served on the EPA Administrator's Advisory Committee on Toxic Substances for the last 4 years, I am impressed with EPA's lack of a comparative risk assessment approach to different toxic chemicals. It is very clear to those who have looked at EPA's mandate under TSCA that the major environmental contributor to toxic chemical risk in the future is asbestos. It is the most proven carcinogen and is expected by experts to be the largest environmental contributor to the future cancer rate.

Yet EPA has not taken regulatory action or other effective risk management action on asbestos, and has scattered its resources in dealing with lesser toxins, less well proven, with lesser exposures. A comparative risk assessment approach would guide EPA toward a more optimal allocation of its resources under BCA; namely, focussing on the high-priority toxins.

This bill could also lead to the solution of the problem of the ad hoc, less than objective analysis; that is, the conveniently different approaches taken by different analysts, or the so-called numbers game. For example, in my studies of the radiation standards set by the Nuclear Regulatory Commission and EPA, both charged with the setting of radiation standards to protect human health, and both using cost-benefit analysis, I found that each agency had its own arbitary value for life—the NRC value of $1,000 a man rem, and the EPA value of $500,000 per life. Other agencies using cost-benefit analysis have also felt the need to quantify human life, and have set other values, each set so as to achieve an analysis which justified a particular outcome.

To those who are willing to accept the cost benefit approach to protecting human health and who accept the need for valuation so long as it leads to principled decisionmaking, this lack of consistency is disturbing. I am not among those who are willing to accept the cost-benefit approach, in part because it has usually involved such arbitrary valuations, the insertion of convenient numbers into analyses. As practiced thus far, cost-benefit analyses are subjective and arbitrary.

Similarly, in setting the discount rate, cost benefit has been abused. How does an agency assess the present monetary value of future costs and benefits across society. Some agencies use a 10-percent discount rate, which OMB has suggested; other agencies use rates ranging from 2 to 20 percent. The outcomes of analyses change according to the numbers that are used in the analyses, and the ease with which the number can be changed, and the outcomes, is very disturbing.

Nevertheless, OMB and the Office of the President have consistently suggested that there be flexibility in running such analyses—

except for the discount rate—because the adoption of generic approaches, or standardization, would reduce the analyst's discretion to reach certain outcomes. Thus, flexibility which leads to ad hoc, low credibility approaches has prevailed over principled decisionmaking. From the perspective of developing sound administrative practices for dealing with risk objectively, this attitude is very disturbing.

Finally, by carrying out activities under this bill, we will begin to see what our alternatives are for dealing with risk. We have several alternatives to rulemaking, many of which we have relied on in the past. These include the common law, of course, and its actions in nuisance, negligence, strict liability, and product liability. We have insurance mechanisms in the private sector, as well as several Government-subsidized insurance models. We have private self-regulation in different formats, such as industrial voluntary standard setting and professional licensing. And we have other forms of Government involvement which are less intrusive than regulation, such as the use of procurement restrictions and the educational and information functions of Government. Finally, we have not fully considered negotiated agreement options for risk management. These options are dealt with in my recent book, "Alternatives to Regulation."

I believe that this bill, through its coherent approach to risk management, will lead to efforts which identify which risks can best be dealt with by nonregulatory alternatives.

Consider but one of several examples of our present regulatory impasse. OSHA, despite the identification of hundreds of carcinogens in the workplace, over the last decade has been able to regulate only 14. It will be decades, if not centuries, before the others are subjected to the OSHA rulemaking process. And then immediately, there will be litigation, challenging each of OSHA's rules.

I suggest that this committee, given the results of the studies mandated by this bill, could begin to formulate a more effective process approach for dealing with workplace carcinogens, a process approach that might rely on collective bargaining, workmen's compensation, and tort law. None of those are panaceas, or perfect substitutes for regulation, but with some reforms to each of these alternatives, we might be able to set them in motion as ongoing risk management processes which would be more effective for dealing with workplace carcinogens than the substance-by-substance regulatory process which now overwhelms OSHA.

Therefore, I favor enactment of this bill because I think it will improve our science and our law. It will help to bring about new coherence and effectiveness to risk management.

Thank you.

[The prepared statement of Mr. Baram follows:]

TESTIMONY OF MICHAEL S. BARAM

ON

H.R. 3441 - "RISK ANALYSIS BILL"

September 24, 1981

I am pleased to have this opportunity to offer my comments on H.R. 3441, the "Risk Analysis Research and Demonstration Act of 1981." I am a partner in Bracken and Baram, a law firm which specializes in regulatory law; and serve on the faculty of the Boston University School of Law where I direct research on regulatory reform and risk management.

Over the last few years, I have completed several major studies of regulatory reform and risk management. These include a study of the use of cost-benefit analysis by federal agencies for the Administrative Conference of the United States; a report on alternatives to regulation for managing health and safety risks for the Ford Foundation and the National Science Foundation; and a study on the legal framework for dealing with carcinogenic substances for the Congress' Office of Technology Assessment.*

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*M. Baram, Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis, report to the Administrative Conference of the United States (1979); M. Baram et al, Alternatives to Regulation for the Management of Risks to Health, Safety and Environment, report to the Ford Foundation and U.S. National Science Foundation (1980); and M. Baram and J.R. Miyares, The Legal Framework for Determining Unreasonable Risk from Carcinogens, report to the Office of Technology Assessment, U.S. Congress (1981).

Today, I testify as an individual who has been deeply involved in the legal and policy aspects of risk management.

My overall impression of H.R. 3441 is that it is an important step towards meeting an urgent need of the times --- the need for improving public and private sector assessments of risk and for strengthening the quality and credibility of our efforts to manage risk by regulatory and other means.

The bill promotes activities which can also lead to more cost-effective regulation of health, safety and environmental risks; and to a more rational allocation of our fiscal, technical and human resources for managing risks on the basis of their significance.

Thus, I favor enactment of the bill because it can provide useful results for two of the major problem areas facing Congress and the nation today --- risk management and regulatory reform.

Risk management is a major concern in many sectors, as you know. Advances in medical and health sciences, biomedical and environmental monitoring, and other fields are providing new information on potential health hazards from chemicals and other substances. Similar advances in engineering fields and environmental sciences also lead to the identification of hitherto unsuspected hazards. Thus, many new potential risks are being identified as a result of the progress we are making in many technical fields. In addition, conventional products and structures (such as dams) continue to fail with resulting health and property impacts.

But few generally accepted approaches to identifying and measuring such risks have emerged. Agencies and their consultants, industry

and insurance companies are all grappling with the development of new methods to determine the attributes of such hazards, to measure the levels of human and environmental exposure and potential harms and liabilities.

But most of these numerous efforts have been ad hoc and scattered, and are not generally known to or understood by others engaged in risk management, or by the general public, or by the regulatees or others who generate the risks. Many of these efforts are considered self-serving, of questionable quality, inexplicably different from other risk analyses, or insensitive to humanistic concerns.

Even analysts in the field of risk managment confuse and muddle the distinctly separate elements of risk management. In my opinion, these elements consist of the following:

(1) identifying the risk and determining who is responsible for its managment.

(2) preliminary verification that the risk is of sufficient potential and imminence to warrant further steps towards its analysis and management now.

(3) measuring the risk by means of conducting research and surveys of existing knowledge, gathering and organizing the data, and analyzing the data to reach findings of fact as to the attributes of the expected impacts --- in terms of the types and severity of the impacts, their timing and incidence, and their distribution across different population or environmental sectors.

(4) establishing causation by trying to reach findings of fact as to the linkages in the causal chain between risk sources and the impacts on humans and the environment.

(5) determining alternative mechanisms for managing the risk so that it can be reduced to various levels.

(5) continued...

The mechanisms should include regulatory options such as rule-making, as well as non-regulatory options, such as industrial voluntary actions or the workings of tort law. Care should be taken to establish which of the alternative means are technically feasible and otherwise efficacious and equitable.

(6) determination as to what level of risk reduction is appropriate, on the basis of various factors including public values, the significance and distribution of the risk, legislative history and statutory objectives, the standard of care exercized in the industry or other source of the risk, and other qualitative factors. This is the controversial and subjective step which includes both quantitative and qualitative considerations.

(7) choice of the most cost-effective mechanism, regulatory or non-regulatory, for reaching the desired level of risk reduction within a reasonable time, and its implementation.

This conceptualization of risk management differs from others, which, for example may simply involve some measurement of risk and the subsequent use of risk-benefit analysis to establish a rule or other regulatory decision. I offer this approach, however, for several reasons:

(1) it separates the technical or fact-finding steps from those which involve legal, socio-economic and policy considerations.

(2) it promotes the consideration of alternatives to regulation for managing risk.

(3) it promotes the choice of the most cost-effective means to reaching a risk-reduction goal.

(4) it reminds the risk analyst that the task of risk management in our society is not a cold-blooded, stochastic exercise leading to a quantitative balancing of, for example, the costs to industry and the "dollar value" of the deaths or other health impacts on the public; that risk management in our Constitutional system must be responsive to

(4) continued....

> public values, equitable, and therefore based in part on non-economic and qualitative considerations. Many of these qualitative considerations have been developed in the common law --- such as the "reasonableness" of the actions of the source of a risk, and other principles defining rights, duties and responsibility. It would be tragic if we now departed from our traditional principles, and reduced risk management to a numerical balancing based on fiscal considerations alone.

What the public now deserves is a concerted effort to develop standardized, credible "best efforts" approaches to risk analysis and risk management, which this bill would foster. Among the bill's benefits could be the improved quality and credibility of risk analyses, the proper integration of rational and humanistic considerations, the greater potential for coordination and eventual risk reduction by agencies and the private sector, and cost-effectiveness in the task of risk management --- whether by regulation or other means.

When acceptable techniques of risk management become available and relatively standardized, the agencies, Congress and the public will have the further benefit of knowing how to best allocate our limited resources --- fiscal, technical and human. This benefit would arise from the conduct of comparative risk assessments, a process whereby different risks can be prioritized for management action according to their significance, after being assessed using a standardized analytic approach which produces comparable results.

Thus, current imbalances in the way we commit our limited resources could be remedied. Consider the mandate of the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

Despite expert consensus that asbestos is a proven carcinogen, is the largest environmental contributor to our increasing cancer rate now and for the foreseeable future, and that current exposure levels (e.g. of schoolchildren and teachers in schools laden with asbestos) are alarming, the agency has not yet taken any enforceable actions on asbestos, and has scattered its limited resources in various directions on less-well established toxins with lesser exposure and risk levels. Admittedly, action on asbestos would have serious economic implications, but in terms of achieving a significant reduction in cancer risk, such action would be optimal and cost-effective.

A relatively standardized approach to risk analysis and the conduct of comparative risk assessments could also lead to a resolution of analytical differences between agencies which now confuse the public. For example, the exposure of humans to ionizing radiation is subject to different standards, due, in part to the different analytic assumptions about the dollar value of life that were used by the Nuclear Regulatory Commission (NRC) to govern discharges of radiation, and the EPA to govern ambient environmental levels of radiation. NRC used a cost-benefit analysis approach to reach its discharge standard, and valued human life at $1,000 per man-rem. EPA used a similar analytic approach, but valued human life at "somewhere between $100,000 and $500,000." Other agencies using the cost-benefit approach and desiring to quantify all the elements, have used other dollar values for human life. Even if one assumes that cost-benefit analysis and the valuation of life are proper

steps for these agencies to take to reach their health and safety rules, the variability of the numbers is disturbing, and has led many to consider this type of undisciplined analysis with its arbitrary assumptions a "numbers game."

The analytic methods used by different agencies have also employed other convenient but arbitrary assumptions in order to reach pre-selected results. The discount rate for fixing the present monetary values of future costs and benefits has varied wildly, despite the Office of Managment and Budget's past attempt to require use of a standard rate (10%). Indeed, in a single analysis done by the Council on Wage and Price Stability (since abolished), different discount rates were used --- one for future costs, the other for future benefits.

Analytic discretion to choose different values and rates is therefore another problem that may be dealt with by H.R. 3441, since the activities to be taken under H.R. 3441 could lead to generic principles for analysts to use. Such principles would then serve to prevent ad hoc approaches and other abuses, and lead to greater objectivity in risk management.

By promoting generic principles and thereby improving the objectivity and overall quality of agency uses of risk management, H.R. 3441 would enable the courts to better determine "how matters are proven", to use Judge Harold Leventhal's phrase as to the role

of the courts, in their judicial review of agency regulations on technical matters.*

Further, by linking risk analysis to the systematic consideration of regulatory and non-regulatory means for risk management, as I have suggested earlier, an important regulatory reform could be promoted by H.R. 3441. This reform, which I have been working on, is focussed on the possible use of alternatives to regulation for managing many of the risks that are today being dealt with through cumbersome regulatory processes.**

By alternatives to regulation, I am referring to several means of risk reduction that we have frequently relied on in the past, means which are often better attuned to market forces and which may be more cost-effective and at least as efficacious in reducing risk as government regulation. These alternatives include:

(1) common law:

- nuisance, negligence, strict liability, product liability.

(2) insurance:

- private and government-subsidized insurance;
- bonding, escrow and restoration funds.

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*H. Leventhal, "Environmental Decision-Making and the Role of the Courts", U.Pa.L.Rev., v. 122, p.509 (1974). Also see M. Baram, Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis, report to the Administrative Conference of the United States (1979), which recommended that analytic discretion be structured by the adoption of generic rules by each agency, in order to prevent ad hoc abuses in cost-benefit analysis, and to promote accountability and due process. The Administrative Conference adopted this recommendation at its plenary session in March 1979, 44 Fed.Reg. 38817-38826 (July 3, 1979).

**See M. Baram, etal, Alternatives to Regulation for Managing Risks to Health, Safety and Environment, two volume report to the Ford Foundation and the National Science Foundation.

(3) private self-regulation:

- industrial voluntary standards.
- professional licensing.

(4) government influence:

- use of procurement restrictions.
- education and dissemination of information
- negotiation.

None of these alternatives is a panacea for reducing risk. Each has its defects. Yet for certain kinds of risks and causal conditions, they could function perhaps better than regulation in achieving risk reductions, if somewhat modified in each case.

Consider OSHA and its attempts to regulate the risks of carcinogenic chemicals in the workplace. Hundreds of potential carcinogens have been identified, but under 20 have been regulated by OSHA since 1970. These rules have been costly, take years to develop, are immediately challenged, and have been deemed unduly burdensome or inappropriate by many in industry. It will take OSHA decades, if not centuries, to promulgate rules on just the workplace carcinogens we know of today. And more carcinogens will certainly be identified tommorrow. Is there an alternative to the regulatory rule-making approach?

Yes, we have several obvious alternatives to OSHA regulations which may be better means --- if modified somewhat --- for reducing such carcinogenic risks: for example, worker compensation, tort law, and the collective bargaining process all present opportunities for an ongoing risk management process which may be more effective and less costly and burdensome then OSHA rules.
A systematic analysis of the benefits and limitations of each of these alternatives, and efforts to remove the limitations (e.g. to

cure the inadequacies of worker compensation programs regarding chronic health hazards) by Congress and others could lead to cost-effective, less burdensome, and more efficacious forms of risk management --- forms which involve less federal intervention once they are properly set in place.

As society shifts its focus from the federal government to the private sector for resolving many of today's problems, including risk management, the consideration of alternatives to regulation for managing risks becomes more important. H.R. 3441 could play a central role in promoting the careful selection and use of such alternatives.

Therefore, I favor the enactment of H.R. 3441 in order to improve both our science and our law on the matter of risk. Since the Regulatory Council has been recently abolished, another high-level objective organization will have to be vested with the lead role in implementing its provisions, such as the Congress' Office of Technology Assessment or an entity in the Office of the President. I am pleased that the bill recognizes the role to be played by the National Science Foundation. NSF has initiated its "Technology Assessment and Risk Analysis" Program to improve risk management, and the contributions of its officials and grantees will be critical to the implementation of H.R. 3441.

Someday, risk analysis and other elements of risk management could be "reduced to practice", practice which is generally accepted as sound, objective and credible. Other forms of analysis in engineering and economics, for example, have achieved this status. This may sound utopian, but much progress and learning has been achieved to date by a wide variety of analysts in different settings. H.R. 3441 will bring a coherence to these scattered efforts and lead to benefits for all interests.

Mr. WALGREN. Thank you very much, Mr. Baram. We appreciate that testimony.

Mr. Gregg?

Mr. GREGG. No questions.

Mr. WALGREN. Mr. Ritter?

Mr. RITTER. Thank you, Mr. Chairman.

Thank you very much, Mr. Baram, for your excellent testimony. I agree fully with you, I think if Mr. Miller and the regulatory review group focused entirely on cost benefit, they are going in a similar direction as has been gone in the past and to a large extent has failed. When you start putting dollar signs on human legs and limbs and lives, you end up alienating populations which, true or not, feel that they could be the target of that loss.

I think there is some rationale for a cost-benefit approach, but my bill does not take a cost-benefit approach. I think if they ignore this approach, they're going to make a great mistake. This approach is an approach that deals with health effects; this approach deals with the comparative health effects, of different risks, or analyzing the health effects of a given risk and in the standard-setting process understanding what level of standard gives a particular health effect and how that might relate to what people are accustomed to on a daily basis in their everyday lives.

It assesses risk; that is, it assesses the effects on people's health of a particular hazard, and then it tries to put that particular hazard into perspective so that people can understand, with some better degree of greater knowledge, what that hazard means to them. The people's understanding of hazards is exceedingly important because no government policy is going to succeed unless they have the support of the people. And I don't care if it's this administration or another administration; we are trying here in this subcommittee to add into this equation of regulatory reform the better understanding of the health effects of hazards and then putting that understanding in perspective with what people experience on a daily basis—like driving to work, like walking down stairs, like drinking, like smoking, like overeating.

The really unique and different work that has been done in this subject matter is not in the better analyses of assessing the risks themselves, but it is putting the risks in perspective. This is the work of Professor Wilson at Harvard, Professor Wildawski at Berkeley, Lester Lave, and people like that. That's what we're interested in here. We need to assess risk because you can't compare it if you don't know how to assess it. So your techniques for assessment have to be better, have to be enhanced, have to be made more accurate, more intelligent. That is why we assess risk.

But to me, the very bottom line here is being able to then go to the public and say "this is what it means to you in terms of what we know." It's a very, very far cry from cost benefit analyses. I am glad you made that point.

I yield to the chairman at this point.

Mr. WALGREN. Thank you, Mr. Ritter.

Have we ever, in our efforts to control risk, tried to develop the private sector incentives other than the general common law? Are there good examples of what we have done in that area that you could tell us about.

Mr. BARAM. Over the last 3 years, there have been some efforts to more coherently involve the private sector. The Consumer Product Safety Commission and EPA have both started looking at how the private sector manages certain types of risks. EPA, for example, is trying to determine whether private insurance is an alternative for dealing with toxic chemicals. CPSC has been trying to foster industrial voluntary approaches to product risks. But there has been no concerted approach, and these have been isolated, ad hoc efforts.

In some cases, going to the private sector seems to make a lot of sense for certain kinds of risks. In other cases, it may not. But no one knows right now when it makes sense and when it doesn't make sense.

I think the most important implication of this bill is that it can lead to results which point out that there are categorically different kinds of risk, different levels of risk, different public attitudes, and different categorical solutions which we have available, and not all of them are regulatory. A lot of them might very well be nonregulatory, private sector solutions.

Mr. WALGREN. Well, I am interested in the fact that we haven't apparently pursued that very intensively as a government, but instead, I gather, have just sort of relied on the immediate, ad hoc regulation.

The concept of the seven steps is interesting. It would be interesting to compare the regulatory decisions that have been made by the Government with whether or not they went through and did a reasonable development of each of the seven steps. My guess is that that very rarely happens and instead you have a special interest being able to circumvent one step or another simply because of personal closeness or personal influence or specific influences.

Mr. BARAM. Yes. I think we have to keep our eye on the ball, as the late Judge Leventhal suggested, when he said the role of the courts, in reviewing agency decisions on technically uncertain problems, is to determine how matters were proven. Neither the courts nor Congress can get into all the details and all the substantive depth that the agencies can, but they should know the steps that were taken, how matters were proven, and they should want to assure that principled, best efforts approaches are taken to risk management by the agencies. This bill could provide this assurance.

If this bill leads to standardized and principled approaches, it will help the agencies, the courts, and Congress in coping with risks, and could eventually lead to nonregulatory or cost effective regulatory approaches.

Mr. WALGREN. It is kind of a concept of due process, that if people can agree on the process, then you have a broader acceptance of the result of the process regardless of what it is.

Mr. BARAM. Definitely. We must set forth the principles to assure proper agency practices.

Mr. WALGREN. And particularly in ar area where it is a close call or where we are getting to the point that scientists really cannot prove causation but, rather, talk in terms of probability and the like. If you can agree on the process, you would get a broader

agreement among the people who have to pass on the results of that process than if you disagree on the process.

I think this is what Mr. Ritter's point is to the previous witness, that if we don't have a process on which we agree, then—you know, he may have the votes this year and the other side may have the votes next year, and the private sector is going to be pulled between the two posts without any ability to have some certainty for the future of their economic activities. That uncertainty in itself will be very harmful.

If we could get out of this business where we are in an arm-wrestling match, and into a more reasonable positive process where we could at least respect the procedure that the opposing side used, then certainly we might get broader agreement among Congressmen to support the results of that process.

Mr. BARAM. Yes. I think the objectives of the regulatory relief team in the White House and OMB are honorable but different from the broader objectives of this bill and of this committee. Their objectives are limited to economic analysis and deregulation where it makes sense economically. This committee is obviously concerned with improving our analytic process, and by improving our analytic process, improving risk regulation and public acceptance.

Mr. RITTER. Will the chairman yield for a comment?

Mr. WALGREN. I would be happy to yield.

Mr. RITTER. I think your comment about some agreement on the process is very well taken. Particularly as it will impact eventually in the courts, I think it will have a very salutary impact if this bill achieves what its goals are set out to achieve.

I am very disturbed by the kind of litigation that is going on now and the responsibility of judges to make decisions that are so far away from their areas of knowledge. The present process, which is really in some regards no process at all, but a matter of who has the upper hand at any given time I think is a disaster for the courts.

In these health, safety, and environmental questions that are coming down to the courtroom levels, I think we have attorneys and judges who are just way out of their element and in need of some real help and relief in terms of what the ground rules are for making some of these kinds of decisions. It is just not there.

I again think Mr. Miller is mistaken if he feels that we can solve everything in this area with cost-benefit analysis.

Mr. WALGREN. It strikes me that maybe something that would come out of this would be a broader agreement on who the finder of fact ought to be. That, of course, is where the courts may be over their head or perhaps there is a better process or a better body that could be the finder of facts. The courts are notorious in being able to respect a fact once it is found, providing the process by which it is found is one that is within the law.

Perhaps if we were to look at this we might want to be creating some different kinds of fact finders whose decisions would then be treated with the discretion or given the discretion that might be necessary in the area.

Mr. RITTER. If the gentleman will yield again, in my own mind perhaps the primary reason for generating legislation of this kind was precisely to get out from under the cost-benefit bind, that it

was simply too readily available for litigation, that it was too value-laden. One person's cost may be another person's gain. I think we need this legislation precisely because cost-benefit analysis is not sufficient.

Mr. WALGREN. Thank you.

Well, we certainly appreciate having the benefit of your experience and your testimony will be made a part of the record in full. You have shed a great deal of light, so thank you very much.

Mr. BARAM. Thank you.

Mr. WALGREN. The next witness is Dr. Lester Lave, senior fellow at the Brookings Institute, and professor of economics at Carnegie Mellon University. Dr. Lave, welcome to the committee. We both have Pittsburgh roots and we appreciate your making yourself available to us.

[A biographical sketch of Mr. Lave follows:]

LESTER B. LAVE

Lester B. Lave was born in Philadelphia, Pennsylvania in 1939. He received his B.A. from Reed College (1960) and Ph.D. from Harvard University (1963). He has taught at Harvard University, Northwestern University, and the University of Pittsburgh, and was chair of the Department of Economics of Carnegie-Mellon University from 1971-1978. Dr. Lave is presently a Senior Fellow in the Economic Studies Program at the Brookings Institution and Professor of Economics at Carnegie-Mellon University.

Dr. Lave has received grants from both government agencies and foundations to support policy research on health care, the environment, automobile safety, bargaining behavior, the value of information dissemination, and energy, among other social issues. He has been a consultant to almost every Cabinet-level department as well as many private firms, and is a member of various professional associations. Dr. Lave has served on committees of the National Academy of Sciences and the American Association for the Advancement of Science. He is author of more than 150 publications, including two new books: The Strategy of Social Regulation and The Scientific Basis of Health and Safety Regulation. In addition, Dr. Lave is an associate editor of several journals.

STATEMENT OF DR. LESTER B. LAVE, SENIOR FELLOW, BROOKINGS INSTITUTION, AND PROFESSOR OF ECONOMICS, CARNEGIE-MELLON UNIVERSITY, PITTSBURGH, PENNSYLVANIA

Dr. LAVE. Thank you, Mr. Chairman.

Let me start off by saying that I support H.R. 3441 and think that it ought to get passed and ought to get passed soon. But we must recognize what it is and some of the things that it isn't.

It isn't as ambitious as Executive Order 12291, which Jim Miller discussed, and it is not as ambitious as S. 1080, the so-called Laxalt bill, which is modeled on the Executive order. That doesn't mean that it is not necessary, as Jim Miller concluded. After all, Executive Order 12291 only covers those agencies that report to the President. It does not cover, for example, the Federal Trade Commission which Jim Miller is about to head. So there would be a reason to pass the bill, just as there is a reason why Senator Laxalt introduced his bill, to cover all of the agencies and simply not those reporting to the President.

While the bill is not as ambitious as these other two, it sets out the ground rules of what is absolutely necessary for reforming regulation. It provides a systematic approach and it requires the agencies to do additional data collection. It requires them to pay a good deal more attention to analysis and to tradeoffs. Finally it requires them to set priorities.

The best managed of the agencies have done all of those things. They have set out their systematic approaches, they have collected their data, they have done their analysis, and set their priorities. But the average is very different from the best.

My greatest criticism of the bill is that it is too modest. It is asking us to study what we already know how to do. The bill delays everything for 1½ years for unnecessary study. Let me point to four sources where those answers can be gotten.

The first is the Supreme Court decision in *Benzene*, where the Supreme Court required OSHA to go ahead and establish that there was a significant risk and that its regulation would lower that significant risk. Despite the fact that OSHA argued that it could not quantify the risk of worker exposure to benzene, the Supreme Court ordered them to do that.

The OSHA statute is not one that stresses balancing; indeed, the language of the act seems to indicate the opposite. It asks that workers be protected over their lifetime. The only part in the statute that the American Petroleum Institute finds to justify its contention that balancing is required is that requiring that the statute had to be feasible.

The Supreme Court's decision in this case also looked at a common law doctrine. There had to be some significant effect or else it was not worthwhile to regulate.

A second place where visits have been analysed is the various reports done by the Council on Wage and Price Stability and the Regulatory Analysis Review Group. In both of those groups there were extensive analyses of proposed regulations which quantified the risk, more or less badly, but then with all due respect, this bill will require analyses that will quantify the risk more or less badly.

The analyses of COWPS and RARG have been reasonably effective, both in convincing the agency that it ought to change its regulations, or in convincing the President that he ought to intervene in some cases.

The COWPS and RARG analyses that they encompass are not restricted to economic regulation; the whole field of health, safety and environmental regulations. In all of those cases, COWPS and RARG were able to quantify the nature of risk.

A third place to go for some answers is a study under a contract between the American Petroleum Institute and Carnegie Mellon Univeristy that I headed. It examines quantitative risk analysis for carcinogens, scrutinizing the current methods available. Six case studies of recent regulatory decisions that involved risk analysis what role risk analysis has played in one of those studies.

That study found that currently available tools allow quantitative risk assessment for carcinogens. There is not universal agreement on the details of how end method is to be applied or precisely how to interpret the outcomes. Yet, the kind from those analyses is helpful in thinking about regulatory decisions.

Finally, a fourth place to go for information is a book on regulatory analysis just published by the Brookings Institution. It arose from a question posed to me by Charlie Schultz and Frank Press in the last administration. Food additives is one of the most emotional areas for consumers. The question was, "Is there some way to bring some quantitative, systematic analysis to the area?"

My study looked at five food additives and at a number of other regulatory analyses that had been done by government. It found that even in the most controversial areas that risk analysis is possible, that it generated highly useful information. But one should not deceive oneself that risk analysis is definitive; it doesn't point to a unique outcome or tell you precisely what to do. That is, it gives useful but not definitive information.

That then takes me back to Executive Order 12291 and S. 1080. I started out by saying this bill was less ambitious than either of those. To some extent, this is to Mr. Ritter's credit. The Executive order in particular suffers from a sort of hubris that economists are often guilty of—I can certainly confess for myself in an earlier reincarnation—believing that we can identify the most cost-beneficial outcome; that is, the alternative with the highest net benefits, that we can then prescribe which alternative ought to be uniquely identified and adopted, which is what the Executive order requires.

I have had a good deal of experience in doing benefit-cost analyses and in helping government agencies do them. I am not sure I have ever found a case where one could uniquely identify the alternative that had the highest net benefits.

Cost benefit analysis, like risk analysis, can develop information which is highly useful in the decision, but it cannot be prescriptive. In various versions the Laxalt bill has sometime had this hubris and some times not.

Well, let me then conclude by saying that I think the bill is a good one; it should be adopted. I advise dropping the requirements for the 18 month study. Many agencies have sufficient experience with risk analysis already. In addition, those agencies under the President's control have been required to do a full regulatory anal-

ysis, including assessment of visits since February 17. I don't suggest that everyone has been doing it well, but at least the requirement would be nothing new. Even the agencies that are not under the President's direction have pledged that they would try to do something of this sort, so again, there is no new requirement. I don't see any reason to hang back and pussyfoot around: The time has come to adopt such a requirement.

If anything, the language of the bill could be strengthened by requiring the risk analysis to be done by full-time personnel within the agency; it should prohibit contracting for the analysis. It is very important that the analysis be done in-house, in real time with the decision, that it be done by people who are trusted by the Administrator of each agency, and who can communicate with that person. These analysis must be done in-house.

Finally, there is a need for a government agency to exercise oversight over the whole process. At the moment the only agency that is a candidate is the Office of Management and Budget, particularly the President's Regulatory Task Force. There are many problems with locating it in such a central office, but the benefits outweigh the risks.

[The prepared statement of Dr. Lave follows:]

Testimony of Lester B. Lave
before the
Subcommittee on Science, Research, and Technology
of the
House Science and Technology Committee
September 24, 1981

As a student of regulatory reform, I support HR 3441 and hope it can be swiftly enacted. The health, safety, and environmental statutes passed during the 1960s and 1970s are long on social purpose, yet short on the realities of costs, benefits, and trade-offs. A nation with finite wealth and competing demands on its resources must pierce through rhetoric and focus on what each regulation can do to serve the public interest and at what cost.

The area where government is most sensitive and where regulatory agencies have been most reluctant to quantify effects have been for risks. In its brief to the Supreme Court, OSHA argued that it need not quantify risks and that attempting to do so was difficult or impossible because of the remaining uncertainties. The Court answered that OSHA could not regulate until it found a significant risk and presumably found that its regulation significantly reduced this risk.

HR 3441 does not require, and the Supreme Court decision in benzene and later in cotton dust did not require, that the benefits of risk reduction be shown to exceed the costs. Attempting to translate health effects into dollars adds a layer of uncertainty to already cloudy estimates; it is nonsense to treat the estimated costs and benefits as if they were point estimates in which the agency could have enormous confidence. In earlier testimony before this committee, I

criticized Executive Order 12291 as placing a greater burden on the tool of benefit-cost analysis than it can bear.

HR 3441 requires explicit analysis of risks as an input to regulatory decision making. This is an important input and, if the risk analysis is done in a timely fashion within the agency, should influence the ultimate decision. It is a modest version of Executive Order 12291 and of S 1080. Since the Executive Order requires a full benefit-cost analysis, it necessarily includes an analysis of risks. Thus, HR 3441 would have its principal effect on the independent regulatory agencies which are not covered by the Executive Order; for the agencies reporting to the president, the bill would remind agencies that Congress is particularly concerned about the risk elements of benefits and costs.

S 1080 is more modest than the Executive Order and gives a more realistic appraisal of what benefit-cost analysis can do. If S 1080 were enacted, then the only function of HR 3441 would be to emphasize that Congress is concerned with risks. In that case, I do not believe that much purpose would be served by enacting HR 3441.

Some changes in the proposed bill are necessary. It is my understanding that the Regulatory Council ceases to exist on September 30, 1981. Its functions have been assumed in large part by the Vice Presidential Task Force on Regulation and by the Office of Management and Budget. Thus, the bill cannot assign the Regulatory Council functions. I would suggest that the task force be assigned these functions.

HR 3441 proposes a relatively modest approach to risk analysis, initially attempting to demonstrate that this analysis can be accomplished by select agencies. This step is far too modest. EPA has demonstrated that it can routinely estimate risks in connection with Section 112 of the Clean Air Act, as well as TSCA and FIFRA. OSHA demonstrated in its Supreme Court Brief that it could estimate the risks of occupational exposure to benzene. The FAA routinely estimates risks associated with aviation. The list goes on and on. There is no need to demonstrate that risk analysis can be done when most of the regulatory agencies are currently doing it for at least some aspects of their activities.

If desired, a relatively modest study could be done to survey the risk analyses being done by the various agencies, including the methods used and their effects on agency decisions. However, I see little reason to continue doubting that this tool can be applied and will prove helpful.

In a study of quantitative risk analysis done for a contract between Carnegie-Mellon University and the American Petroleum Institute, I and a group of researchers examined the methods of quantitative risk analysis in addition to six case studies where some form of the tool had been used by regulatory agencies or entered into the record. A subsequent conference at the Brookings Institution aired this material before academicians, company scientists, government scientists, and congressional staffs. While there were many comments about the levels of uncertainty associated with risk analyses, there was no doubt that the analyses could be done and, at least to a modest

extent, would inform agency decisions.

In particular, risk assessment is needed to structure priorities among the myriad toxic substances and accident hazards that each agency is responsible for regulating. For example, there are more new chemicals introduced into the workplace each year than could be tested in animal bioassays. Risk assessment is a better method, despite its uncertainties, than current uninformed guesses. In addition, risk assessment is needed to discover whether current risks are "significant" and if so, what are the most cost-effective ways to lowering the risk. I say all this while at the same time accepting the major uncertainties and ambiguities associated with the method. It is a systematic scientific approach in an area that has been governed by rather arbitrary guesses.

Thus, I recommend the swift enactment of HR 3441 and hope that it will be modified to speed the application of risk analysis to agency decisions.

Mr. WALGREN. Thank you very much.

Mr. Ritter?

Mr. RITTER. I'll pass for a moment. I am just collecting some thoughts.

Mr. WALGREN. One of the things that troubles me is that I, as a Member of Congress, am not really willing to hand over to the executive the judgment unless the judgment is really defined in many parameters. I guess I just don't trust someone else, and I guess I feel that I'm kind of invested by the public with a trust, the public has certain expectations of Congressmen to be ultimately responsible, so we cannot delegate too much.

I guess what troubles me is that at this point there hasn't been developed to my knowledge a guide for me to make those judgments. It might very well be there is risk assessment being done in the executive branch someplace. The problem may be there is not risk assessment being done in the legislative branch. And instead, I am confronted with a special interest coming to me and saying "My gosh, we have got to be able to sell tomatoes; let us sell tomatoes." That's a very difficult position to be put in.

Do you see any ability to develop a framework that legislators could use in this area?

Mr. LAVE. Your comment is a very good one. Let me try and illustrate by reminding you of source legislative history.

In the 1970 Clean Air Act, Congress was feeling particularly suspicious of the executive branch and executive branch agencies.

Against its better judgment, Congress decided to set the emissions standards for automobiles, itself; for stationary sources, it allowed EPA to set the standards.

Congress made a mistake in taking on that detail for itself. The hearings were time consuming and Congress didn't have the expertise to understand the technical arguments and resolve contradictory testimony on the feasibility of standards. Congress should have delegated the responsibility to EPA, but at the same time maintained its oversight hearings, the task that Congress is supposed to fulfill. Congress should question the EPA Administrator in some detail about how the various standards were set and then ask other groups to comment. Congress cannot do risk assessments or even evaluate them. It can oversee the process, to determine if agenies are do what they were instructed to do and if the instruction accomplish what is intended.

Enacting statutes, insuring that agencies are carrying out the statutes and revising statutes in light of experience is the essence of Congress job.

This bill ought to designate an individual in OMB as having the responsibility for developing the methods and reporting back to Congress at periodic intervals about what has been done. With written reports and oversight hearings, you can have as much control as you desire. If problems develop, new legislative can currect them.

My friend Peter Hutt points out that there is a vast amount of agency discretion in each statute; it could not be otherwise. In the few statutes where Congress has been very specific, such as the Delaney Clause of the Food, Drug and Cosmetic Act, the agency almost invariably finds these too constraining.

Even, for example, in language defining the primary air quality standards for EPA, that language is too constraining. Those statuatory provisions reflect the scientific knowledge at the time the legislation is written, but science changes rapidly, unless Congress is prepared to change the statute every few years, it must give discretion to each agency. Congress needs to clarify how it wants value conflicts to be resolved.

Mr. WALGREN. Mr. Ritter.

Mr. RITTER. You have basically said that the techniques or the process of risk assessment, risk analysis, is presently at a high enough level to, in essence, take this bill one step further and look more toward the application of the technique in the proper area.

We hear that the techniques are still very preliminary and that there is a substantial amount of work that continues to be necessary. I guess you're the first person who has really come before us and before me and said, "We're ready to go." Would you comment on that?

Mr. LAVE. Of course there are remaining uncertainties and needs for greater research, particularly with regard to visit. But let me differentiate between saying the last word in science and having a tool useful for regulatory decisions. Most of the important agencies have done risk assessments in recent years. Even though OSHA claimed a risk assessment couldn't be done for benzene, there was one in the record and OSHA provided another in their Supreme Court brief. How could the court fail to reject the augument that

with assessment is infeasible? In every case there remain important uncertainties. Risk assessment can in never provide a confident point estimate. But it can and does quantify the magnitude of risk and pinpoint the important issues where assumptions are necessary.

If you're going to wait for that uncertainty to be resolved, there will never be an H.R. 3441. Neither 18 months of study nor 18 lifetimes uncertainties.

For example, in carcinogenesis one of the big problems is how do you extrapolate from laboratory animals receiving high doses of a carcinogen to human beings receiving a low dose. There are two big steps that have to be taken there. One is going from rodents to human beings and the second one is going from high doses to low doses. Conceptually, there is no difficulty in specifying how to make the steps. All you have to do is know enough about the comparative physiology of rodents and humans to infer how to translate rodent respones. All you have to do is know enough about the mechanism by which that carcinogen acts to get from high doses to low doses.

Neither of those two bits of scientific knowledge are likely to be learned within the next 18 months.

In practice analysts use range of models and make a range of assumptions. We can clarify the models; we can clarify the assumptions. But we cannot now say which is "correct" and will not be able to do so for quite some time.

My assertion is that risk analysis done on the basis of these somewhat arbitrary models and somewhat arbitrary assertions is very helpful right now. It is not definitive. It will not be definitive for some time to come. But it is helpful and I think you ought to go ahead and require that it be done. This kind of helpful input should be available to the agency as it makes its decision and be available to Congress as it exercises its oversight responsibility.

Mr. RITTER. I am also a little concerned about the OMB approach, in that they are still a budget office and to them, therefore, cost benefit is somehow a "god". We are really talking about something else. We are talking about health effects, we are talking about assessing risk, we are talking about comparing it. And yet you have advocated that the institutional home should be in that regulatory review group.

We have kind of come to that conclusion, too, but I think more by default than by real desire. Plus I think we understand where the power is. But if these folks are just driven by cost benefit and not by some of these other concepts, is there some other place or some other way—how do we hold their feet to the fire?

Mr. LAVE. Well, the second question is the easiest to answer. You hold their feet to the fire by your oversight. If the bill gets passed—and I hope it will—you should require inputs and hold hearing on the extent to which they have implemented the bill, how they have implemented it and how successful it has been. There ought to be a periodic reporting requirement so you can examine a formal report and then be able to question them.

The first question is never troublesome. I haven't come to OMB out of default. I think they are clearly the best agency because they are the budget agency. The coin of the realm is information.

Information is the way to control the Government. OMB needs good information. This bill would provide OMB with vastly better information than they have gotten in the past. OMB will recognize this fact and require sound risk analyses.

Jim Miller said that OMB is "mean and lean"—the agencies may be just "lean." They don't have the resources to do this analysis. They don't have the resources for Executive Order 12291, S1080 or H.R. 3441.

How are they going to get the resources? They will have to come to you: more importantly, they will come to OMB and say for additional staff, or at least a change in the allocation of current staff.

You not only want OMB on your side initially in that kind of a request, but I think you want them on your side on a continuing basis. Since it is OMB which will be the principal user of that information, OMB has the greatest incentive to make sure that it is good information, and to make sure that that process is done well.

Now, if the regulatory task force under Jim Miller or Chris deMuth wants to go on and turn that analysis into a full-scale benefit cost analysis, translating everything into dollars and saying "we believe this alternative has the highest net benefit", that's fine with me. I don't object to that. I don't think that is an activity for serious adults, but opinions differ. That does not sort of obfuscate the fact that it is the risk information that would be developed under the bill. OMB would presumably require that that risk information were done well and provided to them.

Mr. RITTER. That answers my question quite clearly.

I would like to make one last comment. Mr. Baram mentioned that he was disturbed by the inconsistency in Washington. Winston Churchill once said that "Consistency was the hobgoblin of small minds." There is enough inconsistency around here I think to be extended all over the country and all over the world. I would hope that you just keep putting up with it because I think inconsistency is here to stay, unfortunately.

Mr. LAVE. Yes.

Mr. RITTER. Thank you, Mr. Chairman.

Mr. WALGREN. Thank you very much. We appreciate your contribution.

With that, we will close the hearing.

[Whereupon, at 12:03 p.m., the subcommittee was adjourned.]

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